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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2022

OR

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

For the transition period from _____ to _____

Commission file number 001-39244

Vincerx Pharma, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**83-3197402**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
260 Sheridan Avenue, Suite 400 Palo Alto, CA	**94306**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (650) 800-6676

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.0001 par value per share	**VINC**	**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 Section 15(d) of the Act. Yes ☐ No ☒

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

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

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

Large Accelerated Filer ☐	Accelerated Filer ☐
Non-Accelerated Filer ☒	Smaller reporting company ☒
	Emerging growth company ☒

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

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

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

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

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

The aggregate market value of common stock held by non-affiliates (based on the closing sale price on The Nasdaq Capital Market on June 30, 2022) was approximately $19.8 million.

As of March 28, 2023, there were 21,245,842 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2023 Annual Meeting of Stockholders, which will be filed with the United States Securities and Exchange Commission within 120 days of December 31, 2022, are incorporated by reference into Part III of this Annual Report on Form 10-K.

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Forward-Looking Statements

This report contains forward-looking statements that involve risks and uncertainties. These statements relate to future periods, future events or our future operating or financial plans or performance. When used in this report, the words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intends,” “forecast,” “goal,” “may,” “might,” “plan,” “possible,” “potential,” “predict,” “project,” “should,” “seeks,” “suggests,” “scheduled,” “target,” or “will,” and similar expressions are intended to identify forward-looking statements, and include but are not limited to:

- our future financial and business performance;
- strategic plans for our business and product candidates;
- our ability to develop or commercialize products;
- the expected results and timing of clinical trials and nonclinical studies;
- our ability to comply with the terms of the Bayer License Agreement;
- developments and projections relating to our competitors and industry;
- our expectations regarding our ability to obtain, develop and maintain intellectual property protection and not infringe on the rights of others;
- our ability to retain key scientific or management personnel;
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act;
- our future capital requirements and sufficiency of available cash, including our expected cash runway, the timing of those requirements, and sources and uses of cash;
- our ability to obtain funding for our operations;
- the impact of our strategic prioritization and cost reduction measures;
- the outcome of any known and unknown litigation and regulatory proceedings;
- our business, expansion plans and opportunities; and
- changes in applicable laws or regulations.

These statements are subject to known and unknown risks, uncertainties and assumptions that could cause actual results to differ materially from those projected or otherwise implied by the forward-looking statements, including the following:

- risks associated with preclinical or clinical development and trials, including clinical trials conducted prior to our in-licensing;
- risks related to the rollout of our business and the timing of expected business milestones;
- changes in the assumptions underlying our expectations regarding our future business or business model;
- our ability to develop, manufacture, and commercialize product candidates;
- general economic, financial, legal, political, and business conditions and changes in domestic and foreign markets;
- changes in applicable laws or regulations;
- the impact of natural disasters, including climate change, and the impact of health pandemics and epidemics, including COVID-19, on our business;

- the size and growth potential of the markets for our products, and our ability to serve those markets;
- market acceptance of our planned products;
- our ability to raise capital;
- the possibility that we may be adversely affected by other economic, business, and/or competitive factors, including the impact of inflation and the war in Ukraine; and
- other risks and uncertainties set forth in this report in the section entitled "Risk Factors."

Given these risks and uncertainties, you should not place undue reliance on these forward-looking statements.

Forward-looking statements are subject to a number of risks and uncertainties that could cause actual results to differ materially from those expected. These risks and uncertainties include, but are not limited to, those risks discussed in Item 1A of this report. These forward-looking statements made by us in this report speak only as of the date of this report. Except as required under the federal securities laws and rules and regulations of the Securities and Exchange Commission (the "SEC"), we expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based. You should, however, review additional disclosures we make in our definitive proxy statement for the 2023 Annual Meeting of Stockholders, Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K filed with the SEC.

You should read this report completely and with the understanding that our actual future results, levels of activity and performance as well as other events and circumstances may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

Frequently Used Terms

Unless the context indicates otherwise, references in this report to the "Company," "Vincerx," "we," "us," "our," and similar terms refer to Vincerx Pharma, Inc. (f/k/a Vincera Pharma, Inc. f/k/a LifeSci Acquisition Corp.) and its consolidated subsidiaries. References to "LSAC" refer to our predecessor company prior to the consummation of the Business Combination (as defined below). Additional terms frequently used in this report include the following:

- "ADC" means antibody-drug conjugate.
- "Affordable Care Act" means the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act.
- "AML" means acute myeloid leukemia.
- "ANDA" means an abbreviated new drug application.
- "Bayer License Agreement" means that certain License Agreement, dated October 7, 2020, by and among Legacy Vincera Pharma, Bayer Aktiengesellschaft and Bayer Intellectual Property GmbH.
- "BLA" means a biologics license application.
- "BPCIA" means the Biologics Price Competition and Innovation Act of 2009.
- "Business Combination" means the Merger and the other transactions described in the Merger Agreement.
- "BTKi" means Bruton tyrosine kinase inhibitor.
- "Bylaws" means our amended and restated bylaws.

- "CDK" means cyclin-dependent kinase.
- "CDX" means cell derived xenograft.
- "Certificate of Incorporation" means our second amended and restated certificate of incorporation, as amended.
- "cGMP" means current Good Manufacturing Practice.
- "CLL" means chronic lymphocytic leukemia.
- "common stock" means our common stock, $0.0001 par value per share.
- "CPT" means camptothecin.
- "DH-DLBCL" means double-hit diffuse large B-cell lymphoma (i.e., DLBCL characterized by translocations of MYC and BCL-2).
- "Earnout Shares" means certain rights to common stock after the closing of the Business Combination that Legacy Holders may be entitled to receive pursuant to the Merger Agreement.
- "Exchange Act" means the Securities Exchange Act of 1934, as amended.
- "FDA" means the U.S. Food and Drug Administration.
- "FDCA" means the Federal Food, Drug and Cosmetic Act.
- "GAAP" means accounting principles generally accepted in the United States of America.
- "HER2" means human epidermal growth factor receptor 2.
- "HIPAA" means the Health Insurance Portability and Accountability Act.
- "IL3RA" means Interleukin 3 receptor subunit alpha.
- "IND" means an investigational new drug application.
- "JOBS Act" means the Jumpstart Our Business Startups Act of 2012.
- "KSPi" means kinesin spindle protein inhibitor.
- "Legacy Holders" means the stockholders of Legacy Vincera Pharma immediately prior to the Business Combination.
- "Legacy Vincera Pharma" means Vincera Pharma, Inc. prior to the consummation of the Business Combination, which changed its name to VNRX Corp. following the Business Combination.
- "Legacy Vincera Pharma Common Stock" means Legacy Vincera Pharma common stock, par value $0.0001 per share.
- "MCL" means mantle cell lymphoma.
- "MCL1" means a protein coding gene.
- "Merger" means the merger of Merger Sub with and into Legacy Vincera Pharma, with Legacy Vincera Pharma surviving as the surviving company and as a wholly-owned subsidiary of LSAC, which occurred on December 23, 2020.
- "Merger Agreement" means that certain Merger Agreement, dated September 25, 2020, by and among LSAC, Merger Sub, Legacy Vincera Pharma and Raquel E. Izumi, as the representative of the Legacy Holders.
- "Merger Sub" means LifeSci Acquisition Merger Sub, Inc., a Delaware corporation and wholly-owned subsidiary of LSAC at the time of the Business Combination.
- "MTD" means maximum tolerated dose.

- "mRNA" means messenger RNA.
- "MYC" means a family of regulator genes and proto-oncogenes that code for transcription factors.
- "NDA" means a new drug application.
- "NHL" means non-Hodgkin lymphoma.
- "PDX" means patient derived xenograft.
- "public warrants" means warrants originally issued in the initial public offering of LSAC, which were redeemed in April 2021.
- "private warrants" means the warrants issued simultaneously with the closing of the initial public offering of LSAC in a private placement to LifeSci Holdings LLC and Rosedale Park, LLC and the warrants issued pursuant to Section 8.6 of the Merger Agreement.
- "P-TEFb/CDK9" means positive transcription elongation factor beta/cyclin-dependent kinase 9.
- "Securities Act" means the Securities Act of 1933, as amended.
- "SMDC" means small molecule drug conjugate.
- "USPTO" means the United States Patent and Trademark Office.
- "Warrant Agreement" means that certain Warrant Agreement, dated March 5, 2020, between LSAC and the Continental Stock Transfer & Trust Company.

Vincerx®, Vincerx Pharma®, the Vincerx Wings logo design and CellTrapper™ are our trademarks or registered trademarks. This report may also contain trademarks and trade names that are the property of their respective owners.

Summary Risk Factors

Our business is subject to numerous risks and uncertainties that could affect our ability to successfully implement our business strategy and affect our financial results. You should carefully consider all of the information in this report and, in particular, the following principal risks and all of the other specific factors described in Item 1A of this report, "Risk Factors," before deciding whether to invest in our company.

- We rely on the Bayer License Agreement to provide rights to the core intellectual property relating to all of our current product candidates, which agreement imposes significant payment and other obligations on us. Any failure by us to perform our obligations under the Bayer License Agreement could give Bayer AG ("Bayer") the right to terminate or seek other remedies under the agreement, and any termination or loss of important rights under the Bayer License Agreement would significantly and adversely affect our ability to develop and commercialize enitociclib (formerly VIP152), VIP236, VIP943, VIP924, and our other current product candidates, raise capital, or continue our operations.
- Our preclinical development, clinical trials, manufacturing, supply chains, and other operations and business activities, and the operations and business activities of third parties with whom we conduct business, including our contract manufacturers, contract research organizations, shippers, clinical trial sites, and others, have been, and could continue to be, adversely affected by the effects of health pandemics and epidemics, including COVID-19.
- We are substantially dependent on the success of our enitociclib, VIP236 and VIP943, our lead product candidates. If we are unable to complete development of, successfully initiate and complete clinical trials, obtain approval for, and commercialize these lead product candidates in a timely manner, our business will be harmed.
- We are at an early stage in development efforts for our product candidates, and we may not be able to successfully develop, manufacture, complete clinical trials and commercialize our product candidates on a timely basis or at all.

- Our long-term prospects depend in part upon discovering, developing, manufacturing, and commercializing additional product candidates, which may fail in development or suffer delays that adversely affect their commercial viability.
- Results from early-stage clinical trials may not be predictive of results from late-stage or other clinical trials.
- We rely in part on the clinical trial data provided by Bayer in assessing the viability of enitociclib, and such clinical trial data has not been verified by us or any independent third parties.
- 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.
- We require substantial 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, or eliminate one or more of our research and drug development programs or future commercialization efforts.
- Even if approved, our product candidates may not achieve adequate market acceptance among physicians, patients, healthcare payors, and others in the medical community necessary for commercial success.
- If the market opportunity for any product candidate that we develop is smaller than we believe, our revenue may be adversely affected and our business may suffer.
- We face significant competition, and if our competitors develop and market technologies or products more rapidly than we do or that are more effective, safer, or less expensive than the product candidates we develop, our commercial opportunities will be negatively impacted.
- We may expend our limited resources to pursue a particular product candidate, target, or indication and fail to capitalize on product candidates, targets, or indications that may be more profitable or for which there is a greater likelihood of success.
- Clinical trials are expensive, time consuming, subject to enrollment and other delays, and may be required to continue beyond our available funding, and we cannot be certain that we will be able to raise sufficient funds to successfully complete the development, clinical trials and commercialization of any of our product candidates currently in preclinical and clinical development, should they succeed.
- 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 prospects.
- Any product candidates we develop may become subject to unfavorable third-party coverage and reimbursement practices, as well as pricing regulations, including those under the Inflation Reduction Act of 2022.
- We are at an early stage of development as a company and our limited operating history may make it difficult to evaluate our ability to succeed.
- We have incurred net losses since inception, and we expect to continue to incur significant net losses for the foreseeable future.
- The Bayer License Agreement obligates us to make significant milestone and royalty payments, some of which will be triggered prior to the commercialization of any of our product candidates.
- We may be unable to obtain U.S. or foreign regulatory approvals and, as a result, may be unable to commercialize our product candidates.
- Our current or future product candidates may cause adverse events, toxicities, or other undesirable side effects when used alone or in combination with other approved products or investigational new drugs that may result in a safety profile that could inhibit regulatory approval, prevent market acceptance, limit their commercial potential, or result in significant negative consequences.

PART I

ITEM 1. Business.

Corporate History and Background

We were initially formed on December 19, 2018 as a Delaware corporation for the purpose of effecting a merger, share exchange, asset acquisition, share purchase, reorganization, or similar business combination with one or more businesses. From the time of our formation to the time of the consummation of the Business Combination, our name was "LifeSci Acquisition Corp."

On September 25, 2020, we entered into the Merger Agreement. At the effective time of the Merger, each share of Legacy Vincera Pharma Common Stock, other than any Dissenting Shares (as defined in the Merger Agreement), was canceled and the Legacy Holders received (i) 0.570895 shares of our common stock, for each share of Legacy Vincera Pharma Common Stock held by them immediately prior to the effective time of the Merger and (ii) certain rights to additional shares of our common stock ("Earnout Shares") after the closing of the Business Combination.

The Legacy Holders are entitled to receive Earnout Shares after the closing of the Business Combination if the daily volume-weighted average price of our common stock equals or exceeds the following prices for any 20 trading days within any 30 trading-day period (the "Trading Period"), following the closing of the Business Combination: (1) during any Trading Period prior to the forty-two (42) month anniversary of the closing of the Business Combination, upon achievement of a daily volume-weighted average price of at least $20.00 per share, such number of shares of our common stock as equals the quotient of $20.0 million divided by the Closing Price Per Share (as defined in the Merger Agreement); (2) during any Trading Period prior to the six year anniversary of the closing, upon achievement of a daily volume-weighted average price of at least $35.00 per share, such number of shares of our common stock as equals the quotient of $20.0 million divided by the Closing Price Per Share; and (3) during any Trading Period prior to the eight year anniversary of the closing, upon achievement of a daily volume-weighted average price of at least $45.00 per share, such number of shares of our common stock as equals the quotient of $20.0 million divided by the Closing Price Per Share. A total of 90.6% (rounded to the nearest whole share) of the Earnout Shares then earned and issuable shall be issued to the Legacy Holders on a pro-rata basis based on the percentage of the number of shares of Legacy Vincera Pharma Common Stock owned by them immediately prior to the closing of the Business Combination, and the remaining Earnout Shares that would otherwise have been issuable shall not be issuable to the Legacy Holders but in lieu thereof the number of authorized shares available for issuance under the Vincerx Pharma, Inc. 2020 Stock Incentive Plan shall be automatically increased by an equivalent number of shares of our common stock.

The aggregate value of the shares of our common stock received by the Legacy Holders pursuant to the Merger Agreement was $55.0 million and the aggregate value of Earnout Shares that the Legacy Holders are eligible to receive, subject to certain conditions, is an aggregate of up to $60.0 million.

Overview

We are a clinical-stage biopharmaceutical company committed to developing differentiated and novel therapies to address the unmet medical needs of patients with cancer.

We have brought together a management team with over 120 years of combined experience in oncology and a proven track record of successful drug development, approvals, and value creation. Our management team comes from companies like Pharmacyclics LLC ("Pharmacyclics"), Acerta Pharma, AstraZeneca plc ("AstraZeneca"), Bayer, Amgen Inc., Genentech Inc., and Janssen Pharmaceuticals ("Janssen") and have contributed to significant blockbuster exits such as the $7B acquisition of Acerta Pharma's Calquence® by AstraZeneca and the $975M Imbruvica® partnership between Janssen and Pharmacyclics.

Our current pipeline consists of enitociclib, currently in Phase 1, and a proprietary modular bioconjugation platform, which includes a small molecule drug-conjugate, VIP236, in Phase 1, and preclinical next-generation antibody drug-conjugates, VIP943 and VIP924. Our pipeline is entirely derived from the Bayer License Agreement, pursuant to which we have been granted an exclusive, royalty-bearing, worldwide license under certain Bayer patents and know-how to develop, use, manufacture, commercialize, sublicense, and distribute multiple clinical and preclinical stage compounds. We intend to use these product candidates to treat various cancers in a patient-specific, targeted approach. We believe that these product candidates are differentiated from current programs targeting similar cancer biology and, if approved, may improve clinical outcomes of patients with cancer. Certain of the references in this report to preclinical and clinical studies regarding the Bayer assets refer to preclinical and clinical studies conducted by Bayer or other third parties before we in-licensed these assets.

We believe that our differentiated pipeline, along with our management team, position us to successfully develop paradigm-shifting therapies for patients.

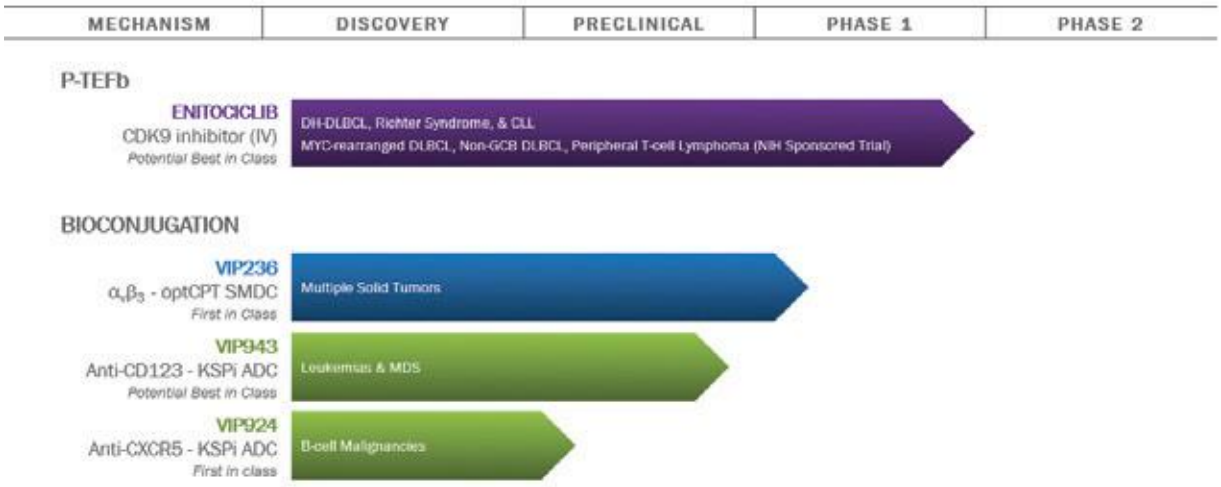
Strategy

Our goal is to develop multiple products through clinical proof-of-concept and potentially through approval in the United States. Our near-term objectives are to:

- Continue the clinical development of enitociclib
- Begin clinical trials with our SMDC (VIP236) in Q1 2023
- Begin clinical trials with our first next-generation ADC (VIP943) in the second half of 2023 and with VIP924 in 2024
- Selectively enter into strategic partnerships to maximize the potential of our pipeline and bioconjugation platform

Our ability to achieve these goals will be dependent on a number of factors as described in the section titled "Risk Factors."

Our Product Candidate Pipeline



P-TEFb Program

Enitociclib, a highly selective CDK9 inhibitor, is designed to be administered intravenously and is in Phase 1 studies in patients with hematologic malignancies.

Scientific Overview of Oncogenes and Transcriptional Regulation in Cancer

Oncogenes (i.e., genes that drive cancer) are induced by mutations of normal genes that result in the loss of normal cell-growth control and lead to the formation of cancers. Expression of these oncogenes often requires dysregulation of transcription (i.e., the biologic process by which genes are activated or regulated) and has been termed "transcriptional addiction." Therefore, agents that can target the transcriptional machinery active in cancer cells may have significant utility in treating patients with cancer. Cyclin-dependent kinases such as CDK7 and CDK9 control transcriptional initiation and elongation, respectively, suggesting that inhibition of these regulators of transcriptional activity may be very effective in controlling cancer.

The first-generation CDK inhibitors developed were relatively nonspecific and are often referred to as "pan-CDK" inhibitors (e.g., flavopiridol and seliciclib) and had non-CDK targets. Although these pan-CDK inhibitors showed great promise in preclinical models, they have proven to have a narrow range of doses that produces therapeutic response without causing significant adverse effects (i.e., narrow therapeutic window) in patients in clinical trials. After the generally disappointing results seen in clinical trials with non-selective CDK inhibitors, the importance of selectivity of compounds for specific CDKs, absence of alternative targets, and patient selection is now widely accepted. For example, three different CDK4/6 inhibitors (abemaciclib, palbociclib, and ribociclib) are now approved for the treatment of metastatic breast cancer. To date, no drugs specifically targeting CDK9 have been approved. However, there are several drugs in clinical trials targeting CDK9, such as dinaciclib, AZD5473, CYC065, KB-0742, alvocidib (formerly flavopiridol), and voruciclib. Dinaciclib was evaluated in a Phase 3 trial of patients with relapsed or refractory CLL and demonstrated clinical activity but did not complete registration studies due to program prioritization decisions by Merck & Co, Inc. Alvocidib (a pan-CDK inhibitor) has been evaluated in Phase 2 trials in AML and has shown signs of clinical activity. Enitociclib was designed to be a highly selective CDK9 inhibitor compared with other agents currently in clinical trials. We believe a highly selective CDK9 inhibitor will have a better therapeutic window than less selective inhibitors.

P-TEFb/CDK9: A Potential Target for Oncology

P-TEFb is an intracellular protein composed of two subunits, CDK9 and Cyclin T, and is a key regulator of RNA polymerase II transcription. Transcription is the process by which the information in a strand of DNA is copied into a new molecule of mRNA. mRNA is then translated into proteins, which are the work horses of most cellular processes.

The inhibition of CDK9, and therefore P-TEFb, blocks this transcription process and leads to the reduction of important cancer-driving proteins, such as MCL1 and MYC, which are oncogenes transcribed by RNA polymerase II. MCL1 is a member of the family of proteins that, when elevated, may prevent the cell from undergoing cell death, otherwise known as anti-apoptotic proteins. MYC is a transcription factor regulating cell proliferation and growth that contributes to many cancers and is frequently associated with poor prognosis and unfavorable patient survival.

To date MCL1 and MYC proteins have not been successfully targeted directly. Both oncogenes have been found to be drivers of several malignancies across solid tumors (e.g., triple negative breast cancer and ovarian cancer) and blood cancers (e.g., DH- DLBCL and CLL). Blocking the transcription of MCL1 and MYC is an indirect way of blocking the activity of MCL1 and MYC by essentially shutting down the production of the proteins at inception.

Enitociclib is designed as a highly selective CDK9 inhibitor that retains its potency in both low and high adenosine triphosphate environments that has shown more selectivity than other CDK9 inhibitors in development, such as fadraciclib, KB-0742, and AZD4573. Enitociclib binds to and blocks the phosphorylation activity of CDK9, thereby preventing P-TEFb-mediated activation of RNA polymerase II and leading to the inhibition of transcription of various oncogenes. We believe this will cause cell death, which may lead to a reduction in tumor cell proliferation.

Enitociclib is the Most Selective CDK9 Inhibitor in Clinical Development

Target	Enitociclib Kd [nM]	Fadraciclib Kd [nM]	Flavopiridol Kd [nM]	KB-0742 Kd [nM]	AZD4573 Kd [nM]
CDK9	**0.57**	**63**	**2.9**	**19**	**0.73**
CDK1	>1000-fold	>10-fold	>50-fold	>10-fold	<10-fold
CDK2	>1000-fold	<10-fold	>250-fold	>10-fold	<10-fold
CDK3	>1000-fold	<10-fold	>100-fold	>10-fold	<10-fold
CDK4-cyclinD1	>250-fold	<10-fold	<10-fold	>10-fold	<10-fold
CDK4-cyclinD3	>100-fold	<10-fold	<10-fold	>10-fold	>10-fold
CDK5	>1000-fold	<10-fold	>10-fold	>10-fold	>50-fold
CDK6	>1000-fold	>10-fold	>250-fold	>10-fold	<10-fold
CDK7	>50-fold	<10-fold	>10-fold	<10-fold	<10-fold
GSK3A	>10-fold	>10-fold	>100-fold	>10-fold	<10-fold
IRAK1	>100-fold	>10-fold	>250-fold	>10-fold	>10-fold

Fold difference relative to Kd values determined for CDK9.

Enitociclib Retains Potency at Low and High Adenosine Triphosphate ("ATP") Concentrations

Compound	Enitociclib	Fadraciclib	Flavopiridol	KB-0742	AZD4573
IC50 (nM) at 10 μM ATP	**4.52**	28.20	**5.96**	29.40	**3.20**
IC50 (nM) at 2 mM ATP	**11.80**	1.670	32.80	1.130	**4.22**

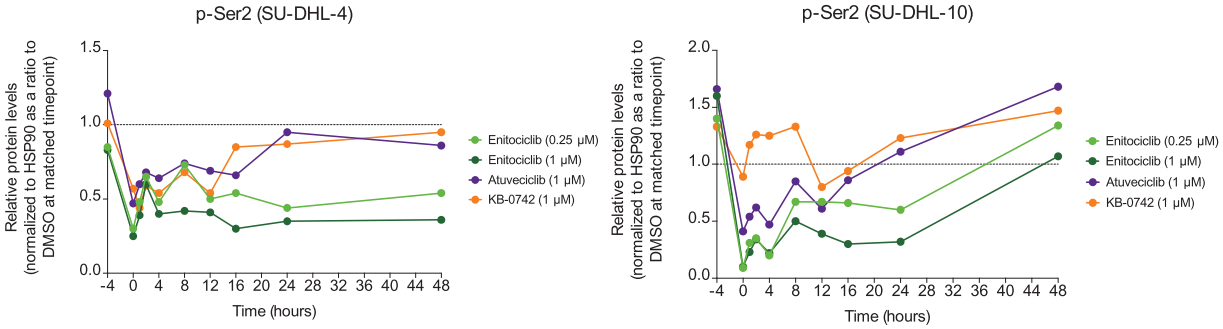
Preclinical Results

Enitociclib Pharmacodynamics in a Multiple Myeloma Mouse Xenograft Model

The pharmacodynamic activity of enitociclib was assessed as a single-drug therapy (i.e., monotherapy) in mice implanted with human multiple myeloma tumors. In this study, a single dose of enitociclib was administered intravenously. After administration, a rapid reduction of MCL1 and MYC mRNA levels and a durable reduction of MYC protein levels were observed, which ultimately induced tumor cell death as marked by increases in processed caspase-3 and down-stream target cleaved poly ADP ribose polymerase (i.e., markers of cell death by apoptosis).

Inhibition of CDK9 results in inhibition of RNA Polymerase II phosphorylation at the Ser2 residue (phospho-Ser2). The figure below shows enitociclib inhibits phospho-Ser2 for 24 to 48 hours compared with <24 hours of inhibition for two other CDK9 inhibitors, atuveciclib and KB-0742.

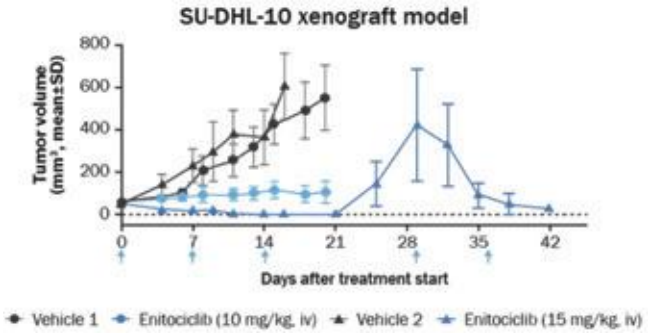
In Vitro Study Evaluating 3 CDK9 Inhibitors (Enitociclib, Atuveciclib and KB-0742) in MYC Expressing DLBCL Cell Lines



In these cell lines, enitociclib at 1 µM also delivered sustained MYC and MCL1 protein depletion for 48 hours, which translated into higher cell kill than observed with the same concentrations of atuveciclib or KB-0742.

The anticancer activity of enitociclib was assessed as a monotherapy in a mouse subcutaneous model of DH- DLBCL. In this study, once weekly doses of enitociclib were administered intravenously. After administration, tumor regression was observed as shown below. In addition, after a period of regrowth, treatment with enitociclib retained its potency.

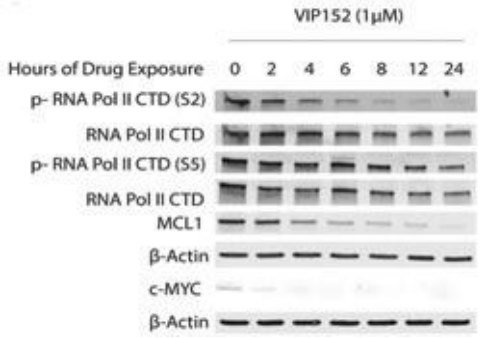
Weekly Infusions of Enitociclib Cause Tumor Regression in DH- DLBCL (SU-DHL-10) Mouse Model



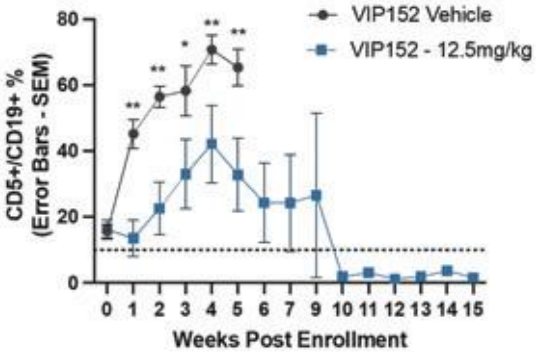
Enitociclib Targets P-TEFb in CLL

CDK9s like dinaciclib and flavopiridol have shown monotherapy efficacy (overall response rate 25%-40%, progression-free survival 7.5-13.7 months) in phase 2/3 trials and, much like venetoclax, enitociclib also targets the anti-apoptotic pathway by down regulation of MCL1. In recent publications done in collaboration with Ohio State University and published in *Leukemia*, we showed enitociclib activity in in vitro and in vivo models of CLL. In a CLL cell line, enitociclib down-regulated the phosphorylation of the CDK9 target RNA polymerase II, resulting in subsequent decrease in protein expression of MCL1 and MYC. In a CLL mouse model, enitociclib reduced tumor burden and improved overall survival. In samples from patients with high-risk CLL who relapsed or were refractory to a BTK inhibitor and venetoclax, enitociclib was cytotoxic, indicating that these parameters should not hinder enitociclib efficacy in a difficult to treat CLL patient population and thus enitociclib may deliver residual disease eradication in combination with a BTK inhibitor.

Depletion of MCL1 and MYC Protein Through RNA Polymerase II Phosphorylation Reduction in HG-3 Cell Line

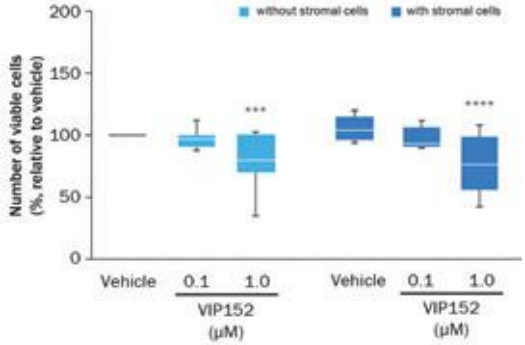


Weekly Dosing Decreases Peripheral Disease in a Circulating CLL Mouse Model



n=10 per arm, * = p <0.05, ** = p <0.005

Cytotoxicity in Cells Derived from CLL Patients Who Are Relapsed and Refractory to Ibrutinib and Venetoclax With TP53 Mutations



Clinical Trials

Study 18117: Enitociclib Dose-Escalation Study in Relapsed and Refractory Leukemia

In a study conducted by Bayer, enitociclib was evaluated in an open-label, multicenter Phase 1 study, which assessed the safety, tolerability, preliminary anti-tumor activity, pharmacokinetics, and maximum tolerated dose of enitociclib in patients with advanced hematologic malignancies. This study was completed early with only 21 patients with relapsed/refractory AML treated (dose levels tested: 5 to 30 mg; 21-day cycles; 30-minute infusions) due to inadequate monotherapy activity in an unselected AML patient population. A similar safety profile was observed across each of the four dose levels explored, with no dose-limiting toxicities reported—the most common adverse events included gastrointestinal side effects and cytopenia. No patients with other hematologic malignancies were included in this study (e.g., CLL or myelodysplastic syndrome).

Study VNC-152-101 (Formerly Bayer Study 17496): Safety, Efficacy, and Expanded Cohorts

Bayer also initiated an open-label Phase 1 dose escalation study (Bayer 17496) designed to evaluate enitociclib as a monotherapy in patients with advanced cancer, including solid tumors and non-Hodgkin lymphoma, after failure of prior standard therapies. The objective of the study was to determine the safety, preliminary antitumor activity, tolerability, pharmacokinetics, and maximum tolerated dose of enitociclib.

The study enrolled 31 patients in the dose escalation portion of the study, then an expansion cohort for DH-DLBCL was opened (n=6). Initial results from this study suggest that single agent enitociclib has a

manageable safety profile, apparent dose-proportional pharmacokinetics, and on-target pharmacodynamic activity. Enitociclib demonstrated a rapid reduction in MCL1 and MYC mRNA in peripheral blood cells. The initial signs of clinical benefit include:

- Stable disease was observed in individual patients with pancreatic cancer and salivary gland cancer (9.5 and 16.8 months of treatment, respectively).
- Of 7 patients with DH- DLBCL treated with enitociclib 30 mg once weekly, 2 patients had complete metabolic remissions (CMR); both achieved CMR after 10 cycles. When treatment ended due to the COVID pandemic (i.e., patients had been in long remission and did not want to risk COVID infection at the hospital), both were still in CMR. One had been receiving treatment for 3.7 years and the other for 2.3 years. Both patients continue in full remission approximately two years after stopping treatment with enitociclib.

In 2021, Vincerx took over the IND and all active trials for enitociclib. The Bayer study 17496 was renamed VNC-152-101 and our team focused on adding new cohorts and enrolling additional patients to the ongoing trial. Due to the promising responses seen in the two patients with DH-DLBCL in the earlier Bayer study, the new cohorts focused on enrolling more patients in this population, specifically patients with MYC-aberrations.

In total, the VNC-152-101study enrolled 63 patients (Bayer enrolled 37 subjects [31 in dose escalation and 6 in a DH-DLBCL expansion] and Vincerx enrolled 26 subjects [Phase 1b in 9=NHL and 17=solid tumors]) at doses between 5 to 30 mg. Below is an overview of the safety and efficacy data for all patients enrolled with a data cut of December 3, 2022.

Total Enrollment by Cancer Type—VNC-152-101

Cancer Type, n(%)	
Appendix	2 (3.2)
Breast	2 (3.2)
Burkitt Lymphoma	1 (1.6)
Chordoma	1 (1.6)
Colon and Rectal	6 (9.5)
DH-DLBCL	11 (17.5)
DLBCL—(Richter syndrome)	1 (1.6)
Esophageal	4 (6.3)
Gallbladder	1 (1.6)
Gynecologic (non-ovarian)	2 (4.8)
Mantle Cell Lymphoma	1 (1.6)
Melanoma	2 (3.2)
Nasopharageal	1 (1.6)
Ovarian	10 (14.3)
Pancreatic	5 (7.9)
Prostate	1 (1.6)
Renal Cell Carcinoma	1 (1.6)
Salivary Gland	1 (1.6)
Supraglottis	1 (1.6)
Triple Negative Breast Cancer	6 (9.5)
Thymoma	1 (1.6)
Transformed Follicular Lymphoma	1 (1.6)
Triple Hit DLBCL	1 (1.6)

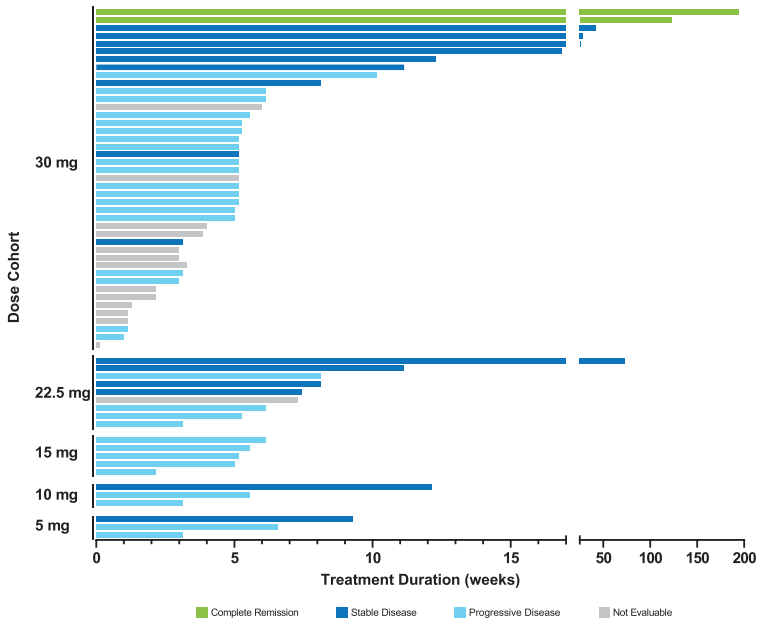
The safety profile of enitociclib monotherapy remains consistent and tolerable, with gastrointestinal adverse events being the most common, along with neutropenia, which is an expected on-target toxicity and is well managed with supportive care. The most common adverse events were Grade 1 and Grade 2. The table below provides an overview of the pooled safety analysis for the 63 patients.

Pooled Safety Analysis Study VNC-152-101: (n=63)

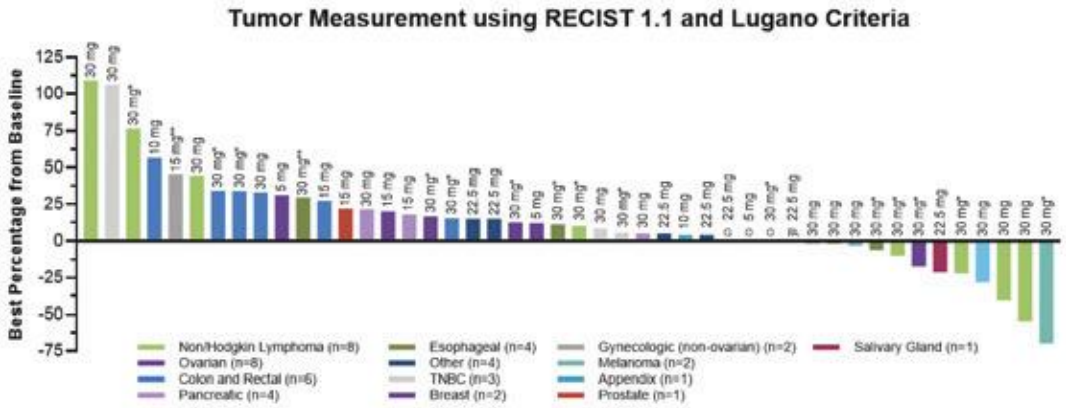
Adverse Events (>15%)	Any Gr n (%)	Gr 1 n (%)	Gr 2 n (%)	Gr 3 n (%)	Gr 4 n (%)	Gr 5 n (%)
Nausea	41(65.1)	24(38.1)	17(27.0)	0	0	0
Vomiting	32(50.8)	21(33.3)	11(17.5)	0	0	0
Fatigue	21(33.3)	10(15.9)	10(15.9)	1(1.6)	0	0
Anemia	20(31.7)	6(9.5)	8(12.7)	6(9.5)	0	0
Diarrhea	22(34.9)	17(27.0)	5(7.9)	0	0	0
Neutropenia	14(22.2)	0	5(7.9)	5(7.9)	4(6.3)	0
Constipation	12(19.0)	9(14.3)	2(3.2)	1(1.6)	0	0

Note: Adverse events selected that were any grade > or equal to 15% incidence

In addition to the two DH-DLBCL patients who achieved a complete metabolic remission, we also observed one patient with transformed follicular and 13 patients with solid tumors who achieved stable disease as a best response: 1 patient with salivary gland cancer (24 cycles), 5 ovarian cancer patients (from 1 to 10 cycles), 2 patients with pancreatic cancer (3 and 14 cycles), 2 patients with esophageal/nasopharyngeal cancer (2 and 3 cycles), 1 patient with appendix cancer (4 cycles), 1 patient with clival chordoma (4 cycles) and 1 patient with breast cancer (3 cycles).



Additionally, we observed reduction in tumor volume across various indications.

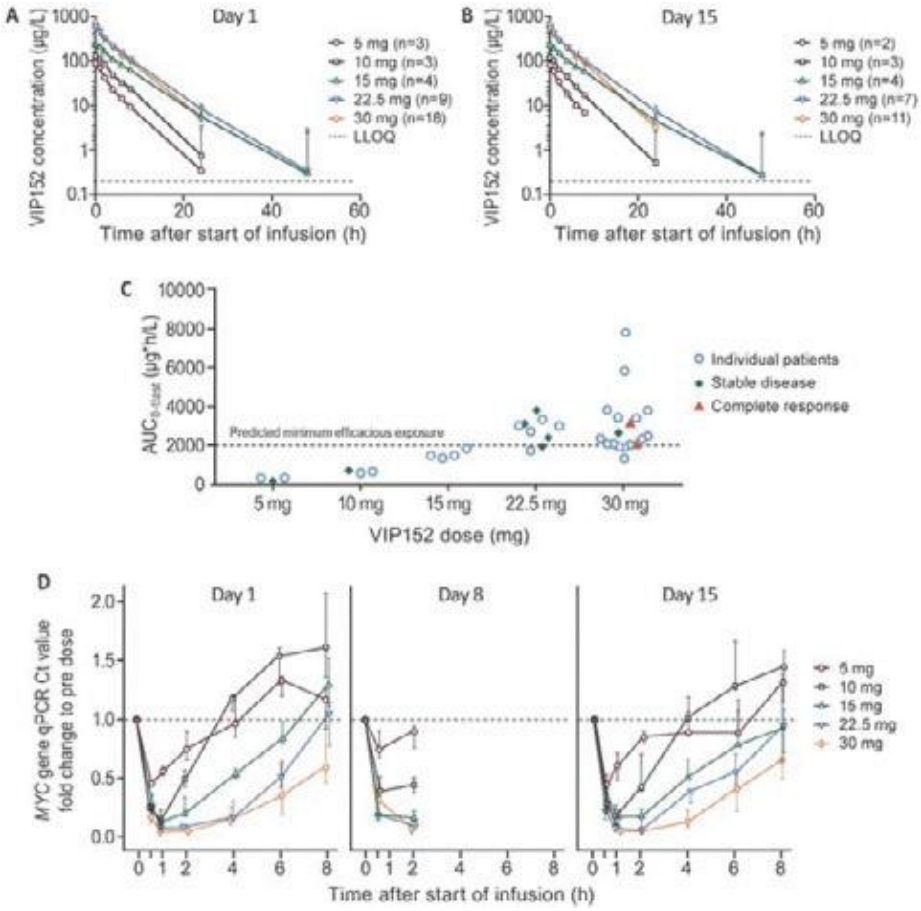


Study VNC-152-101: VIP152 Pharmacokinetics and Pharmacodynamics

The pharmacokinetic and pharmacodynamic effects of enitociclib were evaluated in Study VNC-152-101. After a 30-minute IV infusion of enitociclib, maximum concentrations were typically observed near the end of infusion. Enitociclib exposures were approximately dose proportional, though an overlap in concentrations occurred between the 22.5- and 30-mg doses, likely due to patient variability (Panel A below). At 30 mg, which was declared as the maximum tolerated dose, day 1 AUC was 2780 µg·h/L, which is in the lower range of the predicted minimum therapeutic exposure based on MOLM-13 xenograft studies in rats (Panel C). Enitociclib pharmacokinetics was comparable after single dose (C1D1) and multiple doses (C1D15), with no evidence of significant accumulation or alteration in general pharmacokinetic properties (Panel B).

For all doses, down regulation of MYC (Panel D) and MCL-1 mRNA levels compared with baseline were detected in peripheral blood cells. Down regulation was dose- and time-dependent with maximal pathway inhibition achieved at the two highest dose levels (22.5 and 30 mg).

Enitociclib Pharmacokinetic and Pharmacodynamic Activity in Patient Samples



Study VNC-152-102: Enitociclib in CLL

The introduction and regulatory approval of therapeutic agents targeting BTK as irreversible inhibitors (ibrutinib, acalabrutinib, and zanubrutinib) and BCL-2 (venetoclax) have transformed the therapeutic approach to treating patients with CLL. While beneficial, each of these therapeutic agents offer limitations that greatly impact patients with CLL, in particular patients with del(17p) or TP53 mutations.

When given as a monotherapy or in combination with anti-CD20 antibodies (rituximab, obinutuzumab), BTK inhibitors are administered until the patient progresses or they become intolerant to the drug. Often, this means that patients will remain on treatment for the rest of their lives, never achieving a complete remission. Additionally, the exposure to continuous therapy frequently leads to short- and long-term toxicities from infections, atrial and ventricular arrythmias, hypertension, secondary cancers, and excessive therapy costs. Because of its favorable safety profile and the evidence of monotherapy activity observed thus far, we believe enitociclib could be a good combination partner. Our goal in combining enitociclib with a BTK inhibitor is to put patients on a time-limited treatment, thus limiting a patient's exposure to toxicities and preventing resistance to the BTK inhibitor. This is quite relevant for the del(17p) or TP53 mutated CLL where risk of relapse and death to BTK inhibitor monotherapy is higher over time.

As a first step in our CLL strategy, we began an open-label, multicenter Phase 1/1b study to characterize the safety, tolerability, preliminary antitumor activity, pharmacokinetics, and pharmacodynamics of enitociclib

monotherapy or combination therapy in subjects with high-risk CLL or Richter syndrome. At the American Society of Hematology in December 2022, we presented preliminary clinical data in patients with relapsed/refractory CLL and NHL showing that enitociclib 30 mg had meaningful pharmacodynamic activity in NHL patients and that a dose of 15 mg (in CLL patients) did not demonstrate robust target modulation. The 30-mg dose of enitociclib was well-tolerated by patients with CLL, consistent with previous observations of 30 mg in NHL and solid tumor indications.

Summary of P-TEFb Inhibitor Program

- The most selective CDK9 inhibitor currently in clinical development
- Reproducible down-modulation of MYC and MCL1 mRNA
- Best-in-class safety profile with mainly grade 1-2 toxicities reported
- On-target toxicity of neutropenia is managed by once weekly dosing and supportive care
- Favorable safety profile makes it a viable combination partner in aggressive B-cell lymphomas, CLL/RS and pediatric indications
- Durable complete responses observed in 2 patients with DH-DLBCL for ~5.5 and ~4.0 years, of which 3.7 and 2.3 years were on treatment
- Potential across multiple indications (lymphoma, myeloma, solid tumors)

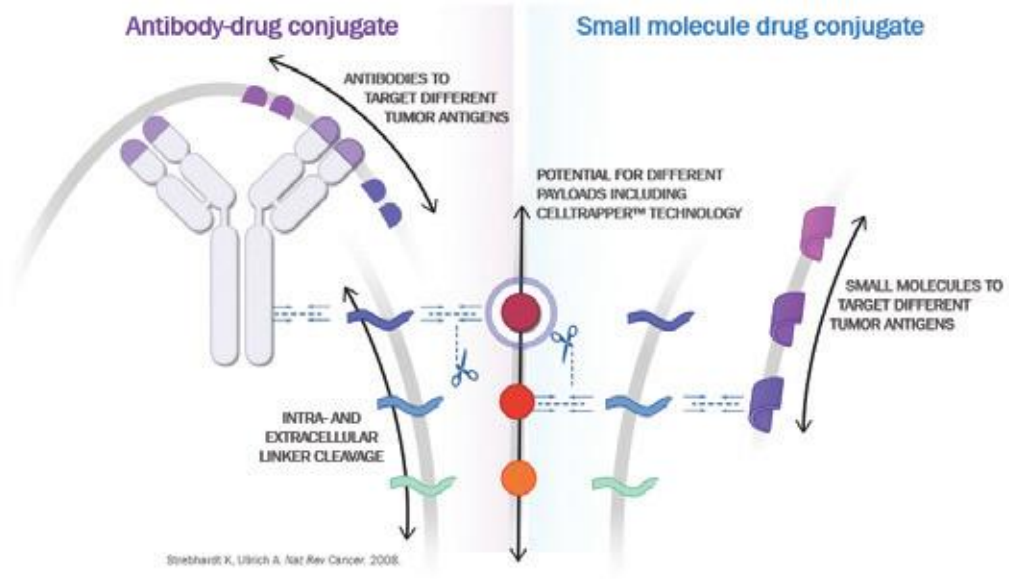
Our Bioconjugation Platform

We obtained from Bayer an exclusive license for a proprietary modular bioconjugation platform that we believe will leverage years of Bayer discovery know-how into innovative treatment modalities. The licensed platform includes a small molecule drug-conjugate, VIP236, currently in Phase 1, and two preclinical next generation ADCs, VIP943 and VIP924, and combines cutting edge payloads and linkers designed to enhance the efficacy and safety of ADCs.

The key features of our bioconjugation platform include:

- Novel linker chemistries for tumor specific payload release by legumain, a protease with a unique cleavage sequence overexpressed in cancers;
- A toolbox of potent payload classes, including KSP inhibitors, with a novel mode of action, to address a broad range of cancer targets;
- Tunable features that allow optimization of a payload's physicochemical profile, to match target tumor biology; and
- Proprietary CellTrapper technology that reduces payload cell membrane permeability so the released payload cannot enter healthy cells.

Our Proprietary Modular Platform: Designing Bespoke Therapies



Small Molecule Drug-Conjugate: VIP236

VIP236 is a first-in-class SMDC with a tailored design intended to efficiently treat patients with aggressive and metastatic cancers. VIP236 binds to activated $\alpha_v\beta_3$ integrin allowing specific homing to the tumor and is efficiently cleaved by neutrophil elastase. Both proteins are present in the tumor microenvironment, are highly expressed in advanced metastatic tumors, and are associated with poor prognosis in patients with cancer. Anticancer activity occurs after a specific and targeted release of an optimized CPT payload by neutrophil elastase in the tumor microenvironment. The CPT payload of VIP236 is optimized for high permeability with low active efflux potential to overcome transporter-mediated resistance observed with SN38, the active metabolite of irinotecan. Other ADCs use irinotecan derivatives as their payload, such as the HER-2 targeting ENHERTU®[1] and TROP-2 targeting TRODELVY®[2]. Irinotecan is currently FDA approved for metastatic colorectal cancer after failure of fluorouracil-based therapy.

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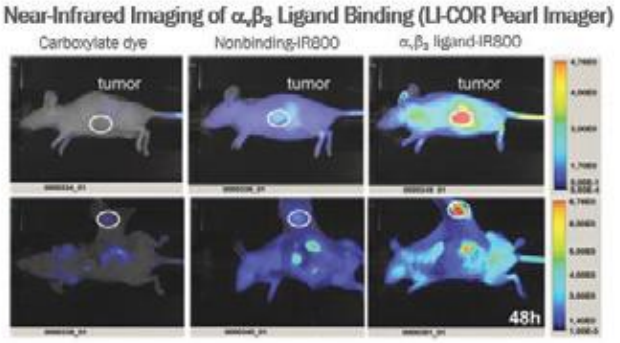
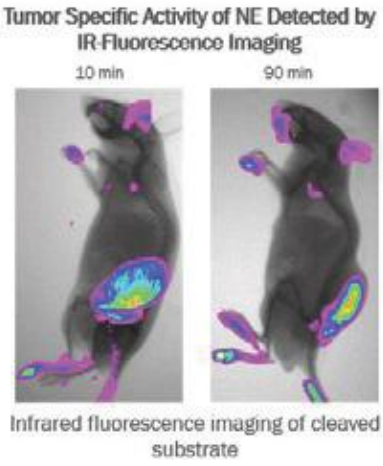
1 ENHERTU® is a mark owned by AstraZeneca plc

2 TRODELVY® is a mark owned by Gilead Sciences, Inc.

VIP236 Specifically Binds to Activated $\alpha_v\beta_3$ Integrin in the Tumor/Tumor Microenvironment and is Cleaved by Neutrophil Elastase in the Tumor Microenvironment

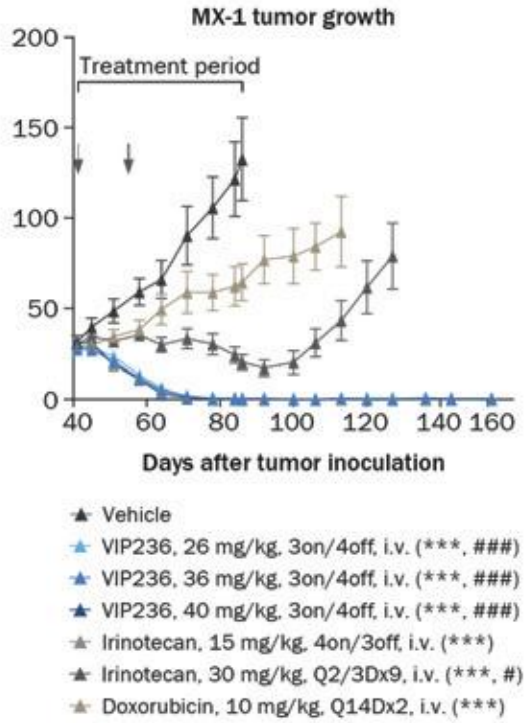




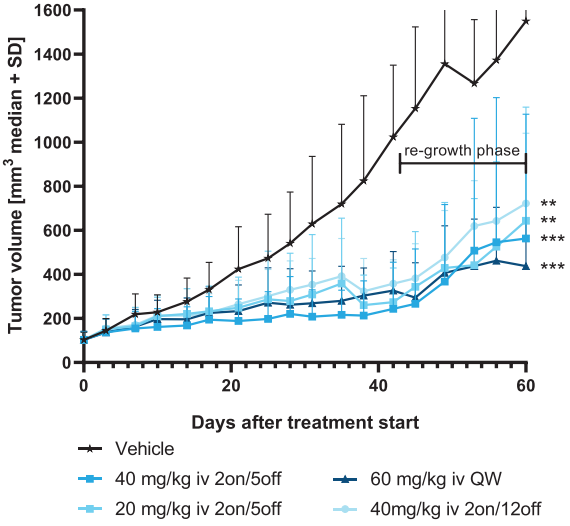
Preclinical Results

We have observed significant and superior tumor regression across various xenograft models with VIP236 treatment compared to standard of care. Select xenograft models for liver metastasis from colorectal cancer and triple negative breast cancer are shown below. In the triple negative breast cancer MX-1 model below, we show that VIP236 has superior tumor regression compared with the common chemotherapies, irinotecan and doxorubicin. In a model of liver metastasis resulting from colorectal cancer, VIP236 caused statistically significant tumor growth inhbition and delayed re-growth.

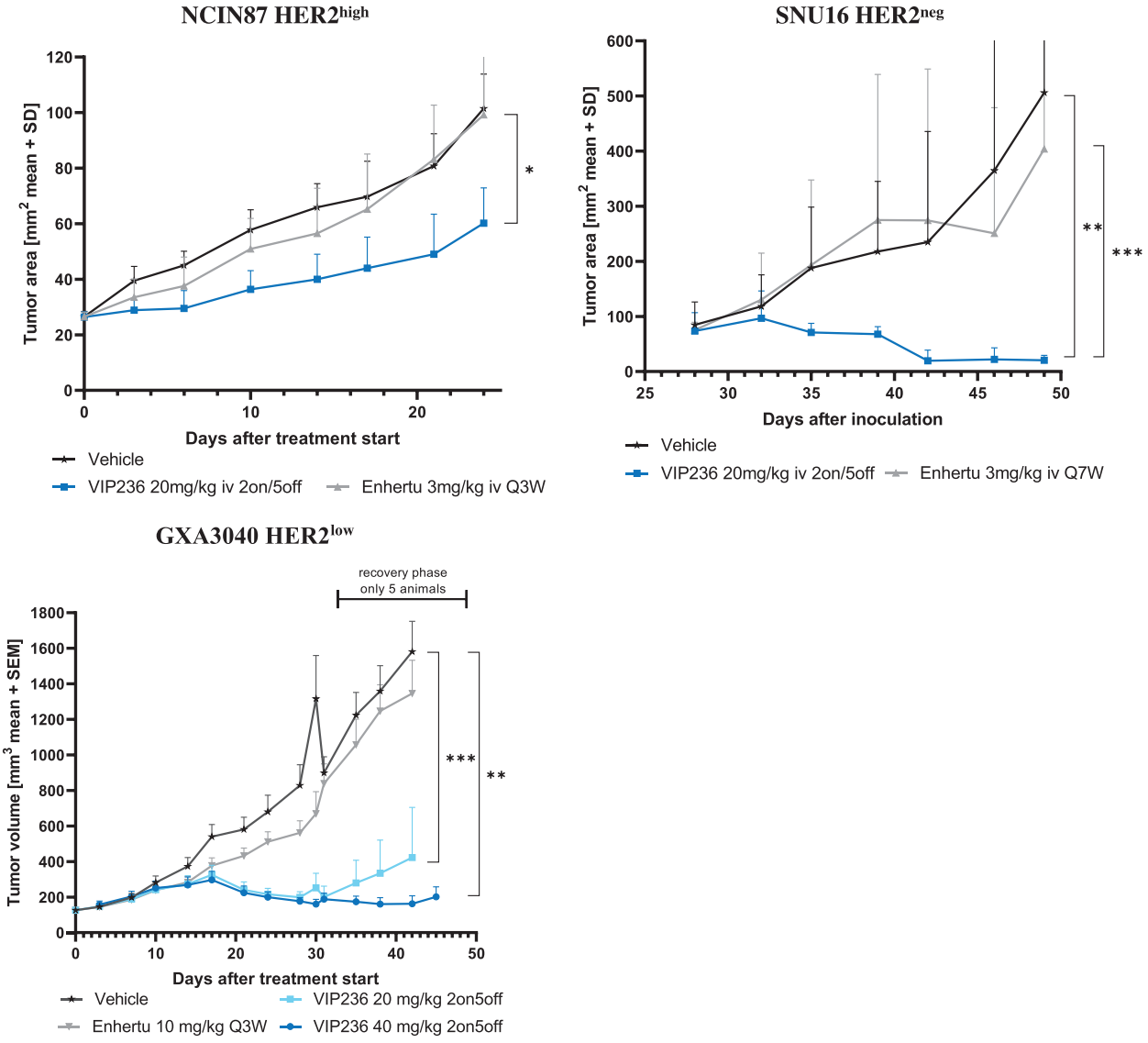
Triple Negative Breast Cancer



Liver Metastasis from Colorectal Cancer



Most notably, we have observed improved in vivo efficacy of VIP236 over ENHERTU (an ADC approved specifically in HER2+gastric and gastroesophageal junction cancer). Our studies show statistically significant tumor growth inhibition with VIP236 in several gastric cancer mouse models independent of HER2 status. In the models shown below, ENHERTU has very little effect on tumor growth, while VIP236 can slow and even cause tumor regression in models no matter the expression of HER2.



Clinical Trials

VNC-236-101: First-in Human Dose-Escalation Study

VIP236 is being evaluated in an open-label multicenter Phase 1 study for patients with advanced cancer. The primary goal of this study is to determine the maximum tolerated dose, safety, and tolerability of VIP236. We began dosing our first patient cohort in Q1 2023.

Summary VIP236:

- First-in-class SMDC designed to selectively bind to tumor cells of metastatic cancers

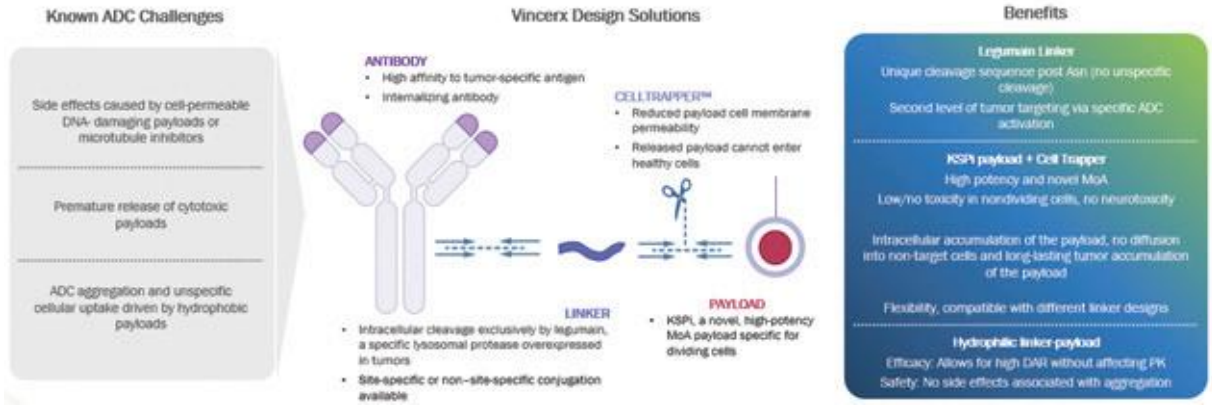
- Payload and linker technology drives tumor selectivity and payload activation
- Optimized camptothecin overcomes SN38 transporter efflux liabilities
- Extracellular linker cleavage by neutrophil elastase provides selective activation
- 10 times greater delivery of payload to tumor
- Demonstrates durable tumor regressions and significant reduction of metastases in vivo
- Proven payload class in the clinic
- IND Safe to Proceed received in December 2022

Next-generation Antibody Drug-Conjugates

ADCs are a validated therapeutic approach in oncology used to selectively deliver a highly potent payload directly to tumors, thereby minimizing toxicity to surrounding healthy tissue. Upon binding to the tumor cell antigen, the ADC is internalized by the tumor cell and the payload is released intracellularly, killing the cell in a targeted manner. To date, there are 12 approved ADCs in the market, over half of which were approved between 2019 and 2022.

Despite the promise of ADCs, the challenge of optimizing the balance between efficacy and tolerability (i.e., therapeutic window) has limited their broad potential as treatments for cancer. In general, currently approved ADCs face three major challenges that impact their efficacy or safety: the poor selection of specific and internalizing antibodies for precise targeting of the tumor, linkers that are prone to cleave non-specifically in circulation or prior to reaching the target cells, and payloads that can diffuse out of target cells and into healthy tissue due to the physiochemical profile of the payload. Additionally, the payload classes currently used are confined to microtubule binders (e.g., auristatin, dolastatin, maytansinoid and tubulysine), DNA interacting agents (e.g., calicheamicin, duocarmycin, PBD and IGN), and topoisomerase inhibitors (e.g., SN38, camptothecin derivatives). Many of these payloads have safety issues, particularly with respect to premature release, and therefore result in an insufficient therapeutic window.

Solving ADC Problems with Innovative Technology



To address these issues, our proprietary modular bioconjugation platform was engineered to specifically address toxicity issues plaguing current ADCs without sacrificing efficacy. First, our linker is exclusively enzymatically cleaved by legumain, which is a lysosomal protease expressed in tumor cells. Specificity of the protease is important to avoid premature release of the payload. So, along with specific cell surface antigen targeting, a second level of tumor targeting occurs due to the selective legumain activity in the tumor cell. Additionally, we believe we are the first company to use a KSP inhibitor as an ADC payload. Kinesin spindle

protein is a motor protein responsible for an essential event in mitosis, spindle formation in the G2/M phase of the cell cycle and is required for productive cell divisions. High expression of kinesin spindle protein in hematologic indications such as AML, DLBCL, and in solid cancers such as breast, bladder, and pancreatic cancer has been linked to poorer prognosis, and thus, kinesin spindle protein presents an attractive target for cancer treatment.

Kinesin spindle protein is active in all proliferating cells and essential for normal mitosis. To date, multiple small molecule KSP inhibitors have been investigated in the clinic but all failed due to subpar safety. These limitations of systemically administered KSP inhibitors are associated with their non-targeted delivery leading to neutropenia, mucositis, and stomatitis in clinical trials. However, targeted delivery of a KSP inhibitor with an ADC approach, combined with our proprietary CellTrapper modification preventing unspecific cellular uptake, has the potential to address the safety problems of systemic KSPi administration. Finally, our proprietary CellTrapper technology enables the payload to accumulate inside the cell versus diffusing into non-target cells. This protects healthy cells and results in less side effects, such as neurotoxicity.

Taken together, we believe these design elements overcome the narrow therapeutic window of systemically administered agents and other ADCs by ensuring targeted delivery and release, as well as ensuring that kinesin spindle protein is only inhibited in cancer cells and not in healthy tissue.

We have two KSPi-ADCs, VIP943 and VIP924, in preclinical development for the treatment of hematologic malignancies:

- VIP943 (CD123-KSPi)
- VIP924 (CXCR5-KSPi)

VIP943 (CD123-KSPi)

Targeting CD123

CD123 is the α-subunit of the IL-3 receptor. IL-3 is a protein, mainly produced by activated T cells, and regulates immune cells by binding to the IL-3 receptor. CD123 is expressed at high levels in AML, classical Hodgkin lymphoma, blastic plasmacytoid dendritic cell neoplasms, and myelodysplastic syndromes. Importantly, CD123 overexpression on AML blasts has been associated with an increased number of leukemic blast cells at diagnosis, which correlates with negative prognosis.

CD123 is a viable target for an ADC approach for the treatment of AML and other CD123-positive hematologic malignancies (e.g., myelodysplastic syndrome, chronic myelogenous leukemia, and blastic plasmacytoid dendritic cell neoplasm). Characterization of hematologic malignancies has demonstrated increased CD123 expression in AML blasts as compared with normal cells. Furthermore, these CD123-overexpressing cells have been shown to initiate and maintain the leukemic process in immunodeficient mice and thus act as leukemic stem cells. Consequently, CD123 has been shown to be a useful biomarker for the detection of minimal residual disease, thereby predicting relapse in patients with AML.

Preclinical Trials

VIP943 is well tolerated in preclinical models—Differentiation of KSPi-ADC Platform

The safety of VIP943 was evaluated in cynomolgus monkeys in two range-finding studies with single or repeated dosing. VIP943 was well-tolerated without adverse events, such as thrombocytopenia, neutropenia, or signs of liver toxicity, typically observed with ADCs containing other payload classes. In addition, mucositis, a dose-limiting toxicity for small molecule KSP inhibitors in clinical studies, was not observed.

These preclinical findings demonstrate the differentiation and potential superiority of the KSPi-ADC platform compared with currently approved ADCs for hematologic malignancies, as the observed clinical toxicities in these approved agents are consistent with the toxicities observed preclinically.

KSPi ADC is Designed to Address Known Safety Challenges of ADCs Approved in Hematologic Malignancies

	MYLOTARG™	BESPONSA®	POLIVY™	ADCETRIS®	VIP943		
PRECLINICAL TARGET ORGAN TOXICITY					Cynomolgus Macaque		
Bone Marrow/Lymph Nodes	+	+	+	+	Not observed		
Liver	+	+	+	+	Not observed		
CLINICAL TRIAL SEVERE ADVERSE EVENTS					Linker	KSPi	CELLTRAPPER™
Myelosuppression		++	++	++	✓	✓	✓
Infections/PML			++	+++	✓	✓	✓
Hepatotoxicity/VOD	+++	+++	++	++	✓		✓
Peripheral Neuropathy			++	++		✓	

+: Present
++: Warnings & precautions
+++: Black box warning
✓: Designed to address AEs

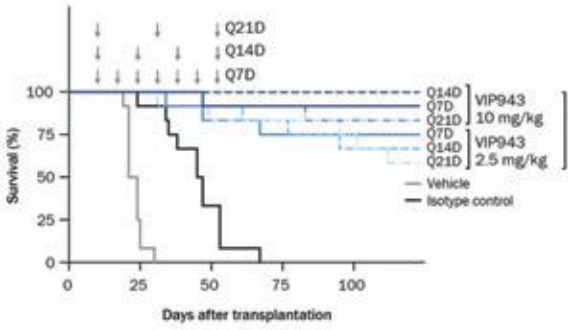
ADC, antibody-drug conjugate; KSPi, kinesin spindle protein inhibitor; PML, progressive multifocal leukoencephalopathy; VOD, veno-occlusive disease.

Source: Drugs@FDA

VIP943 has also shown increased survival in AML tumor models.

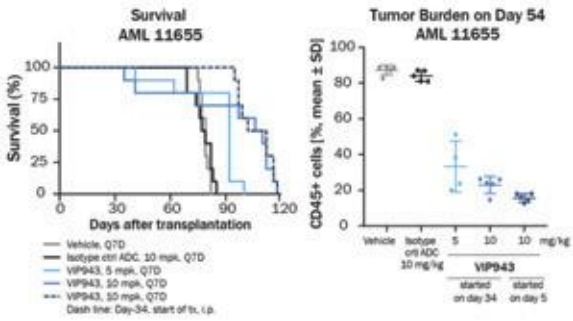
VIP943: IL3RA-KSPi ADC Increases Survival in AML Models

Significantly Improved Survival in AML Model



- Increased survival in disseminated CD123+ AML CDX model MOLM-13, treated Q7Dx7
- Improved efficacy of targeted vs isotype control ADC

Improved Survival and Reduction in Tumor Burden in AML PDX Model

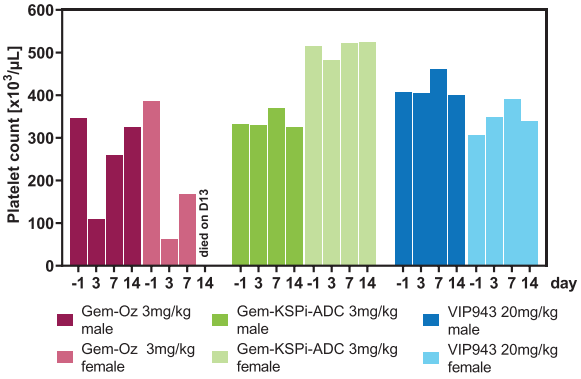


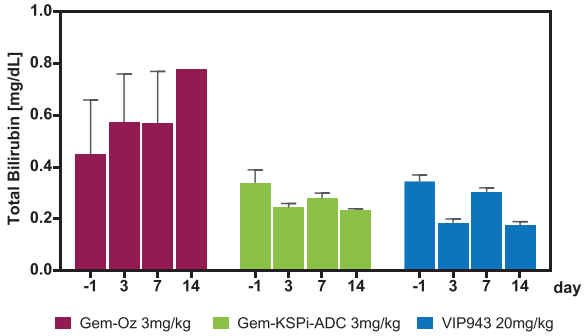
- Increased survival in disseminated CD123+ AML PDX model AML11655, treated Q7D
- Reduction of CD45+ AML tumor burden

At the American Society of Hematology (ASH) 2022 annual meeting, we presented promising data for VIP943 showing, for the first time, a significant improvement in safety over Mylotarg™[3] (an approved anti-CD33 ADC), demonstrating in monkeys the benefit of our linker, KSPi payload and CellTrapper technology. We also showed in vivo efficacy in AML mouse models.

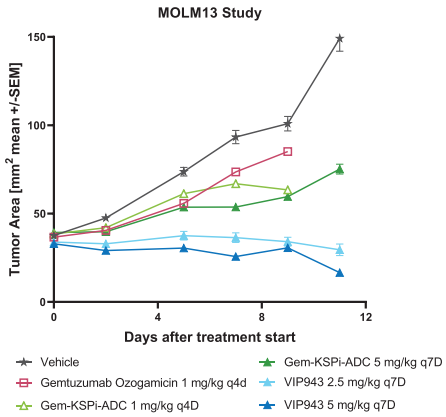
[3] Mylotarg™ is a mark owned by Pfizer Inc.

In the safety study, we compared VIP943 to Mylotarg (gemtuzumab-ozogamycin) and to an anti-CD33 mAb combined with our linker and legumain-KSPi payload (Gem-KSPi-ADC) in monkeys after a single dose. The study showed a critical drop of platelet counts and red blood cell counts with insufficient recovery as well as continuous decrease in white blood cells and lymphocytes in the Mylotarg group. We also observed a critical decrease for hemoglobin and hematocrit in the Mylotarg group, while the KSPi based ADCs showed no effect on cell populations. Additionally, the study showed increased liver enzymes and severely increased total bilirubin for animals treated with Mylotarg, indicating liver toxicity, as well as an extreme increase of urea nitrogen, indicating kidney toxicity. There were no adverse occurrences with ADCs utilizing the legumain-KSPi payload. Ultimately, one monkey treated with Mylotarg had to be euthanized due to adverse event related complications and the other monkey died on day 13 of the study. All four animals treated with our KSPi ADCs were sent safely back to the colony after the end of the study.





The data presented at ASH, also included results of an efficacy study in a MOLM-13 mouse model, which showed that VIP943 had superior efficacy as compared to Mylotarg. In that study, VIP943 achieved tumor regression after 2 cycles with the 2.5-mg/kg and 5.0-mg/kg dose levels, while Mylotarg and Mylotarg with our linker and payload resulted in minor tumor growth inhibition after 3 cycles.



Compound	Treatment schedule	Max. BW loss	RR	CR	PR	SD	PD	T/C
Vehicle	Every 4 days	-0.63%	0%	0	0	0	10	1
Gemtuzumab-Ozogamicin	1 mg every 4 days	0%	0%	0	0	0	10	0.77*
Gem-KSPi-ADC	1 mg every 4 days	0%	0%	0	0	0	10	0.45*
Gem-KSPi-ADC	2.5 mg Q7D	0%	0%	0	0	0	10	0.7
Gem-KSPi-ADC	5.0 mg Q7D	0%	0%	0	0	1	9	0.36
VIP943	2.5 mg Q7D	-0.07%	70%	0	7	2	1	0.11
VIP943	5.0 mg Q7D	-0.65%	80%	0	8	2	0	0.04

Clinical Trials

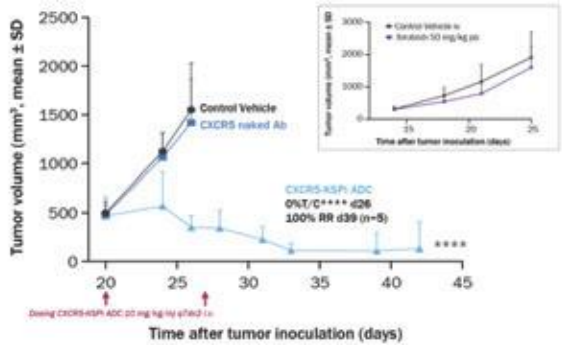
We expect to submit the IND for VIP943 in mid-2023, with the goal of initiating clinical studies in the second half of 2023.

VIP924 (CXCR5-KSPi)

VIP924 is a first-in-class CXCR5 targeted therapy. CXCR5 regulates chemotaxis, germinal center formation, and plasma and memory B-cell differentiation. VIP924 has an internalizing antibody that binds to CXCR5, which is linked to a legumain released KSPi that drives cell death during cell division. The payload targets KSP, stopping cell division and causing catastrophic cell death. Additionally, our CellTrapper modified payload is hydrophilic and accumulates in the tumor cell for improved safety and tolerability for long-term treatment of B-cell malignancies.

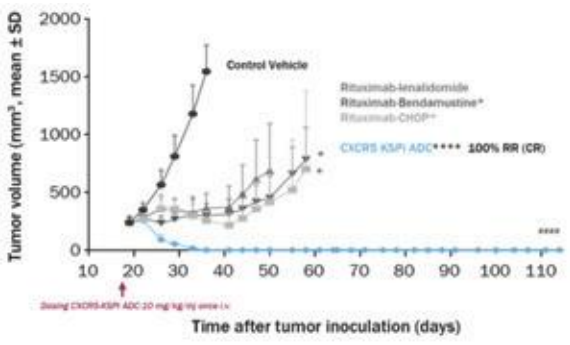
In preclinical studies, VIP924 induced sustained tumor regression in MCL and DLBCL models, including ibrutinib-refractory MCL cell derived models.

VIP924 Is Active in Ibrutinib-Refractory MCL In Vivo Model



- Ibrutinib-refractory MCL CDX CXCR5+ REC-1 model (inset)
- VIP924 achieved complete remission after 2 doses

Single Dose of VIP924 in DLBCL In Vivo Model Achieved Durable Complete Regressions



- Complete regression with single dose of VIP924 in CXCR5+ model OCI-LY1 (day 114)
- Superior activity versus standard of care

Summary of ADC Platform:

Despite recent approvals, currently approved ADCs have a narrower than expected therapeutic window, which limits wider use (e.g., toxicity prevents reaching maximally efficacious dose or severe overlapping toxicities, such as neutropenia, with standard of care).

- Key features of our KSPi-ADC platform were engineered to address the current challenges faced by approved ADCs:
  - Antibodies against overexpressed tumor antigens (i.e., CD123 for leukemias and CXCR5 for B-cell malignancies);
  - A nonpermeable and potent payload (i.e., hydrophilic KSPi) to accumulate in tumor cells and prevent the killing of healthy cells (i.e., payload accumulates in targeted cancer cells but cannot get into healthy cells);
  - A novel linker preferentially cleaved in tumor tissue vs normal cells (i.e., linker only cleaved by legumain, an enzyme over-expressed within tumor cells);
  - Proprietary CellTrapper technology that reduces payload cell membrane permeability so the released payload cannot enter healthy cells;
- Preclinical results for the KSPi-ADCs show efficacy without associated toxicity observed with ADCs approved to date. Specifically, in a monkey toxicology study, VIP943 showed no neutropenia, thrombocytopenia, or liver toxicity, while Mylotarg resulted in significant toxicity and death;
- IND for VIP943 is expected in mid-2023, with first-in-human studies starting in the second half of 2023; and
- IND for VIP924 is expected in 2024.

Sales and Marketing

Because we are a clinical-stage company, we do not currently have our own marketing, sales, or distribution capabilities. To commercialize enitociclib or any future product candidate, if approved for commercial sale and marketing, we would have to develop a sales and marketing infrastructure. We may opportunistically seek strategic collaborations or partners to maximize the commercial opportunities for our product candidates inside and outside the United States.

Manufacturing

We do not currently own or operate manufacturing facilities for the production of clinical or commercial quantities of our drug substances or drug products, and there are a limited number of manufacturers that operate under the cGMP requirements of the FDA that might be capable of manufacturing for us. We currently intend to rely on contract manufacturing organizations, for both drug substance and drug product. In addition, we intend to recruit highly qualified personnel with experience to manage the contract manufacturing organizations producing our product candidates and other product candidates that we may develop in the future. Similarly, we do not own or operate a laboratory with expertise in diagnostic assessment of cancer subpopulations and will contract with specific commercial diagnostic labs on trials performed to assure a companion diagnostic(s) is available to accompany our therapeutic product. We will recruit highly qualified personnel with experience to manage these commercial diagnostic companies for our product candidates or those that we may develop in the future.

Our outsourced approach to manufacturing relies on contract manufacturing organizations to first develop cell lines and manufacturing processes that are compliant with cGMP requirements and then produce material for preclinical studies and clinical trials. Our agreements with contract manufacturing organizations may obligate them to develop a production cell line, establish master and working cell banks, develop and qualify upstream

and downstream processes, develop drug product processes, validate (and in some cases develop) suitable analytical methods for test and release as well as stability testing, produce drug substance for preclinical testing, produce cGMP-compliant drug substance, or produce cGMP-compliant drug product. We will conduct audits of contract manufacturing organizations prior to initiation of activities under these agreements and monitor operations to ensure compliance with these agreements, the mutually agreed process descriptions, and cGMP regulations. A similar approach is applied to commercial diagnostic companies that we would partner with for companion diagnostics.

Competition

The biotechnology industry, especially the oncology subspace, is characterized by fast-paced technological evolution, substantial competition, and a strong emphasis on intellectual property. Competitors may come from multiple sources, including specialty, pharmaceutical and biotechnology companies, public and private research organizations, academic research institutions, and governmental agencies among others. Product candidates that we may develop and potentially get approved will face competitive pressures from incumbent therapies as well as new therapies that may become available in the future.

Many global pharmaceutical companies, as well as medium and small biotechnology companies, are pursuing new cancer treatments whether small molecules, biologics, ADCs, or cell or gene therapies. Any of these treatments could prove to be superior clinically to our products or product candidates and render them obsolete or non-competitive.

Enitociclib

Enitociclib works by targeting the CDK9 of the P-TEFb heteroduplex made up of CDK9 and Cyclin-T. To our knowledge, there are at least six other CDK9 programs in development demonstrating clinical efficacy and several are more advanced than our programs. The companies with clinical-stage programs include Merck & Co., Inc., AstraZeneca, Cyclacel Pharmaceuticals Inc., Kronos Bio, Inc., Sumitomo Dainippon Pharma Co., Ltd., and MEI Pharma, Inc. These companies and their current or future partners may develop CDK9 inhibitor programs with attributes to compete in the same indications as enitociclib.

In addition, there are many other companies that are pursuing targets around the P-TEFb heteroduplex complex to affect similar transcriptional or disease processes as CDK9 inhibition may affect. Companies that are pursuing the inhibition of CDK7, CDK2, MYC, BRD4, PRMT, and related transcriptional regulators may compete in the same indications as enitociclib. These companies and their current or future partners may develop competing inhibitor programs with attributes to compete in the same indications enitociclib.

Bioconjugation Platform

We believe our bioconjugation platform components are well differentiated and provide us the flexibility of creating ADCs, SMDCs, or other variants to address specific needs of individual diseases. Although our SMDC and ADC programs are proprietary and, in our view, highly differentiated, many companies continue to invest in innovation in the ADC field, including new payload classes, new conjugation approaches, and new targeting moieties. Any of these initiatives could lead to ADCs that have superior properties to ours. We are aware of multiple companies with ADC technologies that may be competitive to our bioconjugation product candidates and platform, including Astellas Pharma Inc., AstraZeneca, Bristol-Myers Squibb Company, Daiichi Sankyo Company, Limited, ImmunoGen, Inc., Immunomedics, Inc., Mersana Therapeutics Inc., CytomX Therapeutics, Inc., Pyxis (which acquired Pfizer, Inc.'s ADC technology), and Seagen, Inc. These companies or their partners, including Johnson & Johnson Inc, Roche Holding AG, AbbVie Inc., Genentech, Inc., Eli Lilly and Company, Novartis International AG, Sanofi S.A., and Takeda Pharmaceutical Company Limited, may develop ADCs, SMDCs, or related bioconjugation products based on the unique capabilities of each technology to compete in the same indications as our current and future bioconjugation product candidates.

We expect to compete on efficacy, safety, and tolerability, and if our products are not demonstrably superior in these respects compared with other approved therapies, we may not be able to compete effectively, rendering our technologies, or our product candidates, obsolete or non-competitive.

Many of our potential competitors, either alone or in partnership with other players, have significantly greater financial, technical, and human resource capabilities than us. This in turn might allow them to become more successful than us in achieving treatment approvals and market acceptance, reducing the competitiveness of our product candidates, and accelerating their obsolescence. In addition, merger and acquisition activity in the pharmaceutical and biotechnology space may result in an increased concentration of resources among a smaller number of competitors. Earlier stage companies may also become relevant competitors, especially through collaborations with established companies. The areas of competition also extend to scientific and managerial talent recruitment and retention, clinical trial sites, patient registration for clinical trials, and acquisition or development of technologies that might be complementary or necessary for our drug programs.

The development of a cure or more effective treatment by a competitor for any of the indications being targeted by our product candidates could render our product candidates non-competitive or obsolete, or materially reduce the demand for our product candidates. Our competitors may also obtain FDA or other regulatory approval for their product candidates faster than us, potentially resulting in a stronger market position for their products before we can get to market.

Government Regulation

Regulatory authorities, in the United States as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of small molecule drugs and biologics such as those we are developing.

FDA Drug Approval Process

In the United States, drug products are subject to regulation by the FDA under the FDCA and the regulations promulgated thereunder. Biological products, such as our ADC product candidates, are approved for marketing under provisions of the Public Health Service Act, via a BLA. The application process and requirements for approval of BLAs are very similar to those for NDAs, and biologics are associated with similar approval risks and costs. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as clinical hold, the FDA refusal to approve pending NDAs or BLAs, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

The process required by the FDA before drug product candidates may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's current Good Laboratory Practices requirements;
- submission to the FDA of an IND, which must be reviewed by the FDA before clinical trials may begin;
- approval by an Institutional Review Board or ethics committee for each clinical protocol before clinical trials may begin;
- performance of adequate and well-controlled human clinical trials in accordance with the FDA requirements, to establish the safety and efficacy of the product candidate for its intended purpose;

- preparation of and submission to the FDA of an NDA or BLA after completion of all pivotal clinical trials, and satisfactory completion of an FDA Advisory Committee review, if applicable;
- satisfactory completion of one or more FDA pre-approval inspection(s) of the manufacturing facility or facilities at which the product candidate is produced, tested, and released to assess compliance with cGMP and to assure that the facilities, methods and controls are adequate to preserve the product candidate's continued safety, purity, and potency, and of selected clinical investigation sites to assess compliance with good clinical practice requirements; and
- FDA review and approval, or licensure, of the NDA/BLA to permit commercial marketing of the drug product for particular indications for use in the United States.

Preclinical and Clinical Development

Prior to beginning the first clinical trial with an investigational product in the United States, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational product to humans. The central focus of an IND submission is on an evaluation of safety to support the protocol(s) for clinical studies. The IND also includes results of studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product candidate; chemistry, manufacturing, and controls information; and any available human data or literature to support its use. An IND must become effective before human clinical trials may begin. The submission of an IND may or may not result in FDA authorization to begin a clinical trial. At any point, if the FDA has questions or concerns regarding an ongoing clinical trial, they may impose a clinical hold, for example, until such time as adjustments can be made to that trial conduct to resolve such concerns.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with good clinical practices, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study and the parameters to be used in monitoring safety and efficacy. A separate submission to an existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. For new indications, a separate, new IND may be required. Furthermore, an independent Institutional Review Board for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site and must monitor the study until completed. Regulatory authorities, the Institutional Review Board or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the clinical trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the sponsor, known as a data safety monitoring board, which provides recommendations for whether or not a clinical trial may move forward at designated check points based on access to certain data from that clinical trial and may recommend discontinuation of the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical trial results to public registries. For purposes of NDA/BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

- *Phase 1*—The investigational product is introduced into healthy human subjects or patients with the target disease or condition. These studies test the safety, dosage tolerance, absorption, metabolism, distribution, and elimination of the investigational product, the side effects associated with increasing doses, and, if possible, to gain early evidence on efficacy. For certain investigational products for life-threatening diseases, such as cancer, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, initial human testing is conducted in patients with the target disease or condition.
- *Phase 2*—The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosage, and dosing schedule, and to

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

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

Post-approval trials, sometimes referred to as Phase 4 or post-approval commitment studies, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA/BLA.

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

During the development of a product candidate, sponsors are given opportunities to meet with the FDA. These meetings may be prior to submission of an IND, at the end of Phase 1 or Phase 2, and before an NDA/BLA is submitted. Meetings at other times may also be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development. Sponsors typically use the meetings at the end of the Phase 2 trial to discuss Phase 2 clinical results and present plans for the pivotal Phase 3 clinical trials that they believe will support approval of the new drug.

Additional meetings and correspondence with the FDA can also occur to summarize progress in the clinical trials, to review written IND safety reports, and to develop strategies (for example in accordance with FDA initiatives such as Project Optimus) for dose finding and dose optimization that leverage preclinical and clinical data in dose selection, including randomized evaluations of a range of doses in clinical trials. An emphasis of such strategies is placed on performing these studies as early and as efficiently as possible in the development program.

U.S. Submission, Review and Approval

Assuming successful completion of required testing in accordance with applicable regulatory requirements, the results of product development, and preclinical and clinical studies are submitted to the FDA as part of an NDA/BLA requesting approval to market the product. The NDA/BLA must include all relevant data available from pertinent preclinical and clinical studies, together with detailed information relating to the product candidate's chemistry, manufacturing, controls, and proposed labeling. The submission of an NDA/BLA requires payment of substantial fees to the FDA, unless a waiver or exemption applies. Additionally, no user fees are assessed on NDA/BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA reviews an NDA/BLA to determine, among other things, whether a drug product is safe, pure, and potent and the facility in which it is manufactured, tested, processed, packed, or held meets standards designed to assure its continued safety, purity, and potency. The FDA may convene an advisory committee to provide clinical

insight on application review questions. This review typically takes twelve months from the date the NDA is submitted because the FDA has approximately two months to make a "filing" decision after the application is submitted.

Before approving an NDA/BLA, the FDA will typically inspect the facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the drug product within required specifications. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates an NDA/BLA and conducts inspections of manufacturing facilities where the product candidate and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response letter. An approval letter authorizes commercial marketing of the drug product with specific prescribing information for specific indications. A Complete Response letter will describe all of the deficiencies that the FDA has identified in the NDA/BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response letter without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the Complete Response letter, the FDA may recommend actions that the applicant might take to place the NDA/BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of an NDA/BLA if applicable regulatory criteria are not satisfied, require additional testing or information, and/or require post-marketing testing and surveillance to monitor safety or efficacy of a drug product.

If regulatory approval of a drug product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the NDA/BLA with a Risk Evaluation and Mitigation Strategy to ensure the benefits of the drug product outweigh its risks. A Risk Evaluation and Mitigation Strategy is a safety strategy that is developed to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools. The FDA may also conditionally approve a drug product based on, for example, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the drug product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the drug product reaches the marketplace. The FDA may require one or more Phase 4 post-marketing studies and surveillance to further assess and monitor the product's safety and efficacy after commercialization, and may limit further marketing based on the results of these post-marketing studies. In addition, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could impact the timeline for regulatory approval or otherwise impact ongoing development programs.

In addition, the Pediatric Research Equity Act, requires a sponsor to conduct pediatric clinical trials for most drugs. Under the Pediatric Research Equity Act, original NDAs/BLAs and supplements must contain a pediatric assessment unless the sponsor has received a deferral or waiver. For molecularly targeted oncology drugs, the Research to Accelerate Cures and Equity (RACE) for Children Act (2017) requires an agreement reached with the FDA on which pediatric indications are to be fully assessed with a pediatric study plan. The required assessment must evaluate the safety and efficacy of the product for the selected indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. A deferral may be requested and granted for several reasons, including a finding that the drug is ready for approval for use in adults before pediatric clinical trials are complete or that additional

safety or effectiveness data needs to be collected before the pediatric clinical trials begin. The FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current, or submit a request for approval of a pediatric formulation.

Expedited Development and Review Programs

- Any product candidate submitted to the FDA for approval may be eligible for programs intended to expedite the FDA review and approval process, such as priority review, fast track designation, breakthrough therapy designation, and accelerated approval. Priority review designation may be granted for a product candidate that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness.
- If the FDA determines, based on the request of a sponsor, that a product candidate is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need by providing a therapy where none exists or a therapy that may be potentially superior to existing therapy based on efficacy or safety factors, that product candidate may be eligible for fast-track designation.
- A breakthrough therapy designation is granted to drugs or biologics that are intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that a drug or biologic may demonstrate substantial improvement over existing therapies.
- An accelerated approval determination may be granted for product candidates studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions.

Even if a product candidate qualifies for one or more of these programs, the FDA may later decide that it no longer meets the conditions for qualification or decide that the time period for the FDA review and approval will not be shortened. Furthermore, priority review, fast track designation, breakthrough therapy designation and accelerated approval do not change the standards for approval but may expedite the development or approval process.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition (a disease or condition that affects fewer than 200,000 individuals in the United States) for which there is no reasonable expectation that the cost of developing and making available such a drug or biologic would be recovered from sales in the United States for that drug or biologic). Orphan drug designation may offer a seven-year period of marketing exclusivity, with exceptions. Orphan drug designation does not convey any advantage in, or automatically shorten the duration of, the regulatory review or approval process.

Post-Approval Requirements

Any drug products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things, requirements relating to quality control and quality assurance, record-keeping, reporting of adverse experiences, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the drug product, such as adding new indications or other labeling claims, are subject to FDA review and approval. There are also continuing user fee requirements, under which the FDA assesses an annual program fee for each drug product identified in an approved NDA/BLA. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process

are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP requirements and impose reporting requirements upon us and any of our third-party manufacturers. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain compliance with cGMP requirements and other aspects of regulatory compliance.

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

- restrictions on the marketing or manufacturing of a drug product, mandated modification of promotional materials or issuance of corrective information, issuance by the FDA or other regulatory authorities of safety alerts, Dear Healthcare Provider letters, press releases, or other communications containing warnings or other safety information, or complete withdrawal or recall of the drug product from the market;
- fines, warning letters, or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of drug products; or
- injunctions, consent decrees, or the imposition of civil or criminal penalties.

The FDA closely regulates and actively enforces the marketing, labeling, advertising, and promotion of drug products. A company can make only those claims relating to safety, efficacy, purity, and potency that are approved by the FDA and in accordance with the provisions of the approved label. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising, and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. The FDA does not regulate such off-label uses, but it does restrict a manufacturer's communications on the subject of off-label use of its products.

Marketing Exclusivity

The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. During the exclusivity period, the FDA may not approve or even accept for review an ANDA or an NDA submitted under Section 505(b)(2), or 505(b)(2) by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovative drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder.

The FDCA alternatively provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA, if new clinical studies (other than bioavailability studies) that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages, or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug product received approval on the basis of the new clinical studies and does not prohibit the FDA from

approving ANDAs or 505(b)(2) NDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to any preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and efficacy.

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

Biosimilars and Reference Product Exclusivity

The U.S. Affordable Care Act (2010) includes a subtitle called the BPCIA, which creates an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-approved reference drug product. To date, a number of biosimilars have been licensed under the BPCIA. The FDA has issued several guidance documents outlining its approach to the review and approval of biosimilars.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference drug product was first licensed by the FDA. In addition, the approval of a biosimilar may not be made effective by the FDA until 12 years from the date on which the reference drug product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference drug product if the FDA approves a full BLA for that competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials

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

Other U.S. Healthcare Laws and Compliance Requirements

In the United States, our current and future operations are subject to regulation by various federal, state, and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare and Medicaid Services and other divisions of the U.S. Department of Health and Human Services (such as the Office of Inspector General). For example, we may have to comply with:

- the anti-fraud and abuse provisions of the Social Security Act;
- the false claims laws;
- the privacy and security provisions of HIPAA and similar state laws;
- state and federal anti-kickback and fraud and abuse laws; or
- price reporting and physician sunshine laws.

If our operations are found to be in violation of any such laws or any regulations, we may be subject to administrative, civil, and criminal penalties, for example damages, fines, disgorgement, and exclusion from participation in government programs, such as Medicare and Medicaid, any of which could adversely affect our ability to operate our business.

Coverage, Pricing and Reimbursement

In the United States and foreign markets, sales of any drug products for which we receive regulatory approval will depend, in part, on the extent to which third-party payors provide coverage and establish adequate

reimbursement levels for such drug products. In the United States, third-party payors include federal and state healthcare programs, private managed care providers, health insurers, and other organizations. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid in the United States, and commercial payors are critical to new product acceptance.

We cannot be sure that coverage or reimbursement will be available for any drug product that we commercialize and, if coverage and reimbursement are available, what the level of reimbursement will be. Coverage may also be more limited than the purposes for which the product is approved by the FDA or comparable foreign regulatory authorities. Reimbursement may impact the demand for, or the price of, any drug product. Third-party payors are increasingly challenging the price, examining the medical necessity, and reviewing the cost-effectiveness of drug products, in addition to questioning their safety and efficacy.

Different pricing and reimbursement schemes exist in other countries. In the EU, governments influence the price of drug products through pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of drug products to consumers. Some jurisdictions operate positive and negative list systems under which drug products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical studies that compare the cost effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to establish their own prices for medicines, but monitor and control company profits.

The marketability of any of our approved drug products may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care, the influence of health maintenance organizations, and additional legislative changes in the United States, including the U.S. Inflation Reduction Act, is increasing the pressure on healthcare pricing. The downward pressure on the rise in healthcare costs in general, particularly prescription medicines, has become very intense. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more of our approved products, less favorable coverage policies and reimbursement rates may be implemented in the future.

Healthcare Reform

In the United States and certain foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system, for example, the U.S. Affordable Care Act (2010), which substantially changed the way healthcare is financed by both government and private insurers in the United States. By way of example, certain aspects of the Affordable Care Act seek to lower Medicare and Medicaid spending, potentially including prescription drug spending. We are continuing to monitor any changes to the Affordable Care Act that, in turn, may potentially impact our business in the future.

We are evaluating the impact of the U.S. Inflation Reduction Act ("IRA") on our business. The IRA was signed into law in December 2022, and among other things, it will regulate out-of-pocket costs for Medicare patients with respect to prescription drugs. The discovery and development of both small molecule and biologic drug compounds may be affected with respect to licensing, production, and marketing of such drugs. The FDA will, in the near-term, propose regulations through its rulemaking process, and while that may take several years, the effect on manufacturer rebates to Medicare, Medicare drug price negotiations, catastrophic drug cost coverage, and other aspects of the commercialization of drug products could be significant. We will continue to monitor the implementation of the IRA.

In addition to the foregoing, individual states in the United States have also become increasingly active in implementing regulations designed to control drug 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, mechanisms to encourage importation from other countries and bulk purchasing.

Furthermore, there has been increased interest by third-party payors and governmental authorities in reference pricing systems and publication of discounts and list prices.

FDA Approval and Regulation of Companion Diagnostics

If safe and effective use of a drug product depends on an in vitro diagnostic, then the FDA generally will require approval or clearance of that diagnostic, known as a companion diagnostic, at the same time that the FDA approves the drug product. According to FDA guidance, if it determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or indication, it generally will not approve the drug product or new drug product indication if the companion diagnostic device is not approved or cleared for that indication. The review of in vitro companion diagnostics in conjunction with the review of our proposed treatments for cancer will, therefore, likely involve coordination of review by the FDA's Center for Drug Evaluation and Research and the FDA's Center for Devices and Radiological Health Office of In Vitro Diagnostics and Radiological Health.

Under the FDCA, in vitro diagnostics, including companion diagnostics, are regulated as medical devices. In the United States, the FDCA and its implementing regulations and other federal and state statutes and regulations govern, among other things, medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance. Unless an exemption applies, diagnostic tests require marketing clearance or approval from the FDA prior to commercial distribution. The two primary types of the FDA marketing authorization applicable to a medical device are premarket notification, also called 510(k) clearance, and premarket approval.

The premarket approval process, including the gathering of clinical and preclinical data and the submission to and review by the FDA, can take several years or longer. It 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.

Premarket approval is not guaranteed, and the FDA may ultimately respond to a premarket approval submission with a not approvable determination based on deficiencies in the application and require additional clinical trials or other data that may be expensive and time-consuming to generate, and that can substantially delay approval. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the premarket approval application approvable. The FDA may also determine that additional clinical trials are necessary, in which case approval of the premarket approval application may be delayed for several months or years while the trials are conducted and then the data submitted in an amendment to the premarket approval application. If the FDA's evaluation of the premarket approval application is favorable, it typically issues an approvable letter requiring the applicant's agreement to specific conditions, such as changes in labeling, or specific additional information, such as submission of final labeling, in order to secure final approval of the premarket approval application. If the FDA concludes that the applicable criteria have been met, it will issue a premarket approval for the approved indications, which can be more limited than those originally sought by the applicant. The premarket approval can include post-approval conditions that the FDA believes necessary to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution. Once granted, approval of the premarket approval application may be withdrawn by the FDA if compliance with post-approval requirements, conditions of approval or other regulatory standards are not maintained or problems are identified following initial marketing.

Devices, once placed on the market, remain subject to significant regulatory requirements, including for example, the applicable portions of the Quality System Regulation, which cover the methods and documentation of the design, testing, production, processes, controls, quality assurance, labeling, packaging, and shipping.

The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party, or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The Foreign Corrupt Practices Act also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Additional Regulation

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act, and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical, and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that our suppliers are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect their future operations.

Other Regulations

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

Intellectual Property

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for our current and future product candidates, novel discoveries, product development technologies, and know-how; to operate without infringing on the proprietary rights of others; and to prevent others from infringing our proprietary rights. Our strategy is to seek to protect our proprietary position by, among other methods, filing or in-licensing U.S. and foreign patents and patent applications related to our proprietary technology, inventions, and improvements that are important to the development and implementation of our business. We also rely on trademarks, trade secrets, know-how, continuing technological innovation, and potential in-licensing opportunities to develop and maintain our proprietary position.

We have a license to patents and other intellectual property relating to enitociclib, VIP217, VIP943, VIP924, VIP236, and our other current product candidates from Bayer on an exclusive, worldwide basis under the Bayer License Agreement. The in-licensed portfolio as of December 31, 2022 includes 28 issued U.S. patents, 13 pending U.S. patent applications, 300 issued patents in various jurisdictions outside of the United States and approximately 108 pending patent applications in various jurisdictions outside of the United States. The Bayer License Agreement is described more fully below.

Our in-licensed patent portfolio covering enitociclib consists of issued patents in the U.S., Europe, China, Japan, India, and Mexico, along with issued patents and pending applications in other markets. The issued U.S. patent covering the composition of matter of enitociclib is expected to expire in November 2033, absent any patent term extensions for regulatory delay. With respect to VIP943 and VIP924, we have pending applications

in the U.S., Europe, China, Japan, India, Argentina, Brazil, and Mexico, along with an issued patent and pending applications in other markets covering the composition of matter of VIP943 and VIP924. Any patent that may issue from our pending patent applications related to VIP943 and VIP924 are expected to expire in December 2037, absent any patent term adjustments or extensions. With respect to VIP236, we have pending applications in the U.S., Europe, China, Japan, India, Argentina, Brazil, Mexico, and other markets covering the composition of matter of VIP236. Any patent that may issue from our pending patent applications related to VIP236 is expected to expire in October 2039, absent any patent term adjustments or extensions. In addition, our patent portfolio covering VIP217 consists of issued patents in the U.S., Europe, China, Japan, India, and Mexico, along with issued patents and pending applications in other markets. The issued U.S. patent covering the composition of matter of VIP217 is expected to expire in April 2035, absent any patent term extensions for regulatory delay.

As of December 31, 2022, we own 18 pending patent applications, including six pending U.S. provisional applications, four Patent Cooperation Treaty (PCT) applications, and 10 applications in various jurisdictions outside of the United States. With respect to our product candidates and processes that we intend to develop and commercialize in the normal course of business, we intend to pursue patent protection covering, when possible, compositions, methods of use, dosing, and formulations. We may also pursue patent protection with respect to manufacturing and drug development processes and technologies.

We also rely upon trade secrets, know-how, and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary information, in part, by using confidentiality and invention assignment agreements with our commercial partners, collaborators, employees, and consultants. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with a third party. These agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our commercial partners, collaborators, employees, and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Bayer License Agreement

On October 7, 2020, we entered into the Bayer License Agreement, pursuant to which we have been granted an exclusive, worldwide, royalty-bearing, worldwide license under certain Bayer patents and know-how to develop, use, manufacture, commercialize, sublicense, and distribute, for all uses in the cure, mitigation, treatment, or prevention of diseases or disorders in humans or animals, (i) a small molecule drug platform, including enitociclib, a P-TEFb/CDK9 inhibitor compound, and (ii) a modular bioconjugation platform, including VIP943 and VIP924, next-generation ADC compounds, and VIP236, an SMDC compound. These platforms currently comprise our entire product candidate pipeline. The Bayer License Agreement became effective upon the closing of the Business Combination.

Under the Bayer License Agreement, we paid Bayer an upfront license fee of $5.0 million upon the closing of the Business Combination. In addition, we are obligated to make significant future payments to Bayer upon the achievement of certain development and commercial sales milestones involving license products as well as ongoing royalties on net commercial sales. The size and timing of these milestone payments vary greatly depending on factors such as the particular licensed product, whether it involves a P-TEFb licensed product or bioconjugation licensed product (and which bioconjugation program – IL3RA, CXCR5, SMDC or additional programs), the number of distinct disease indications, the number of different countries with respect to which the milestone is achieved and the level of net commercial sales, and it is therefore difficult to estimate the total payments that may become payable to Bayer and when those payments would be due. If we achieve all of the milestones for each of the countries and disease indications, we would be obligated to pay development and commercial sales milestone payments that range from $110.0 million to up to $318.0 million per licensed product, and upon successful commercialization of at least five licensed products, we could be required to pay

aggregate milestone payments in excess of $1.0 billion. If we partner with a third party and receive development milestone payments from such third party that exceed the development milestone payments we are required to pay Bayer for the same milestones, we are required to pay Bayer a small portion of that excess.

Under the Bayer License Agreement, we are also obligated to pay Bayer tiered royalties on worldwide net commercial sales of licensed products at royalty rates ranging from single digit to low double digit percentages based on escalating levels of net commercial sales in a calendar year, subject to standard offsets and reductions. These royalty obligations apply on a product-by-product and country-by-country basis and end upon the latest of (i) the date on which the last valid claim of any licensed patents expire, and (ii) 10 years after the first commercial sale of the licensed product, in each case, with respect to a given licensed product in a given country.

Under the Bayer License Agreement, we have sole control of, and are responsible for, at our expense, the development, manufacture and commercialization of licensed products. We have agreed to use commercially reasonable efforts, consistent with our business judgment and for a similarly situated company, to develop and commercialize at least one P-TEFb licensed product and two ADC licensed products in certain major markets. We have the sole right, but not the obligation, to control the prosecution, defense, and enforcement of the licensed patents, and Bayer has backup rights to prosecution, defense and enforcement with respect to any licensed patents for which we elect not to exercise such rights.

The Bayer License Agreement will expire on a country-by-country and licensed product-by-licensed product basis on the expiration of the last royalty term with respect to a given licensed product in a given country, unless earlier terminated. We may terminate the agreement for convenience upon 90 days' written notice. Either party may terminate the agreement, either in its entirety or on a licensed technology-by-licensed technology or licensed product-by-licensed product basis depending on the nature of the breach, if the other party materially breaches its material obligations under the agreement and fails to cure such material breach within 180 days of written notice of such material breach, with termination tolled during any period during which a good faith dispute resolution process is being pursued with respect to material breaches other than non-payment. In addition, either party may terminate the agreement immediately upon written notice if the other party files a voluntary bankruptcy petition, is subject to an involuntary bankruptcy petition, or for certain other insolvency events. Bayer may terminate the agreement if we challenge the validity or enforceability of any of the licensed patents.

Human Capital/Employees

We have assembled a management team of biopharmaceutical experts with extensive experience in building and operating organizations that develop and deliver innovative medicines to patients with cancer. Our management team has broad expertise and successful track records in clinical development and approval of cancer therapies. We are led by Drs. Ahmed M. Hamdy and Raquel E. Izumi, two co-founders and biotechnology entrepreneurs who previously leveraged the discovery know-how of an established pharmaceutical company into break-through cancer treatments. Drs. Hamdy and Izumi were instrumental in the clinical development of IMBRUVICA® and CALQUENCE® for the treatment of blood cancers.

Drs. Hamdy and Izumi, and the rest of our management team, are supported by an external team of experienced cancer drug developers, including John C. Byrd, M.D., the Chair of the Department of Internal Medicine at the University of Cincinnati and Chief Medical Officer of BEAT AML, and Brian J. Druker, M.D., Director at Oregon Health & Science University's Knight Cancer Institute School of Medicine. Dr. Byrd serves as chair of our Scientific Advisory Committee, and Dr. Druker serves on our board of directors.

As our core ethos, we believe that our people are our company's greatest asset. We believe that by fostering an open, aware, accepting, and diverse work environment, we will by extension create a responsive, innovative, and successful company. This ethos guides the focus of our human capital objectives and the emphasis we place upon employee retention, inclusive team culture, diversity, equity, inclusion, and belonging. As of December 31,

2022, we had 41 full-time employees globally, 63% of whom hold a Masters' degree or higher and 34% of whom hold an M.D. or Ph.D. Of our 41 employees, 68% were engaged in research and development and 32% were engaged in general and administrative functions. Of our total number of employees, 20% are based outside of the United States in one of three other countries. The median age of our staff was 47, and 73% of our employees are at or over the age of 40. None of our employees are represented by labor unions or covered by collective bargaining agreements.

As an employer, we believe it is our social responsibility to support employees to the best of our ability while at work as well as in their personal lives. We offer market-competitive compensation to our employees based on peer company benchmarks within the biopharmaceutical industry that take into account an employee's role, level of responsibility, and geographical location. Additionally, we offer a 401(k) plan with an employer match feature to support an employee's retirement planning as well as stock option grants and an employee stock purchase plan so that employees can tangibly participate in our success. Our benefits package covers 100% of employee and dependent paid premiums for medical, dental, and vision insurance that start on date of hire, as well as four weeks of paid time off, 17 company holidays, and generous policies supporting sick time and leaves of absence. In 2022, we launched a new benefit for our team called Summer Hours, in which we shortened each Friday to half-working days but continued to pay employees their full day's salary each week from Memorial Day through Labor Day. We offer ongoing learning and development opportunities for our employees, such as sponsoring culture workshops, training, and education resources and programs, as well as other resources to help employees, at all levels feel a sense of belonging and support to achieve their full potential. We believe that our efforts to create a positive work environment allows our employees to thrive and do their best work, which in turn supports our global mission of creating better treatments for patients.

We consider our relationship with our employees to be very good. Our monthly engagement surveys show a strong overall happiness score, with highest rankings for work relationships, team culture, management, and diversity climate. We have a distributed workforce and have embraced remote work since our inception in 2020, and our remote culture remains strong. In 2022, 51% of our employees chose to work full-time remote, rather than from one of our two global offices located in Palo Alto, California, and Monheim, Germany. We believe that our employees and our company benefit from a diverse, inclusive, and safe work environment and that treating our employees well will help reduce headcount turnover and maintain high engagement and morale.

We believe the vast variety of the experiences, backgrounds, and perspectives that our employees bring to their work every day, and our strategy to emphasize diversity and inclusion, make our company stronger. Our employees come from numerous countries, ethnicities, and backgrounds. When surveyed, 39% of our U.S. employees reported they were born outside of the U.S., and 45% of our U.S. employees speak a native language other than English. Women make up 44% of our global workforce and represent 52% of our leadership team (senior director level and higher). Currently none of our employees identify as non-binary, 12% of our U.S. employees identify as LGBTQ+, 9% identify as having a disability, and 3% identify as a U.S. veteran.

Facilities

Our principal executive offices are located in Palo Alto, California, and our lease agreement for such space expires in December 2025. Vincerx Pharma GmbH, our wholly owned German subsidiary, leases space in Monheim am Rhein, Germany. We do not own any real property. We believe that our office space is adequate to meet our current needs and that additional facilities will be available on commercially reasonable terms to meet future needs.

Legal Proceedings

We are not currently a party to any legal proceedings, and are not aware of any pending or threatened legal proceedings against us, that we believe could have a material adverse effect on our business, operating results or financial condition.

Available Information

Our principal executive offices are located at 260 Sheridan Avenue, Suite 400, Palo Alto, CA 94306, and our telephone number is (650) 800-6676. Our website address is www.vincerx.com. The information contained on, or that can be accessed through, our website is not part of this Annual Report on Form 10-K.

We make available free of charge on our website our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports, as soon as reasonably practicable after we electronically file or furnish such materials to the SEC. You may obtain a free copy of these reports in the Investor Relations section of our website, www.vincerx.com. All reports that we file with the SEC may be read and copied at the SEC's Public Reference Room at 100 F Street, N.E., Washington, DC 20549. Information about the operation of the Public Reference Room can be obtained by calling the SEC at 1-800-SEC-0330. All reports that we file are also available at www.sec.gov.

ITEM 1A. Risk Factors.

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

We rely on the Bayer License Agreement to provide rights to the core intellectual property relating to all of our current product candidates, which agreement imposes significant payment and other obligations on us. Any failure by us to perform our obligations under the Bayer License Agreement could give Bayer the right to terminate or seek other remedies under the agreement, and any termination or loss of important rights under the Bayer License Agreement would significantly and adversely affect our ability to develop and commercialize enitociclib, VIP943, VIP924, VIP236, and our other current product candidates, raise capital, or continue our operations.

We have licensed our current core patents and other intellectual property relating to enitociclib, VIP943, VIP924, VIP236, and our other current product candidates from Bayer on an exclusive, worldwide basis under the Bayer License Agreement. The Bayer License Agreement continues in effect on a country-by-country and licensed product-by-licensed product basis until there are no remaining royalty payment obligations in the relevant country and can be terminated earlier by Bayer in the event that we materially breach our material obligations, that bankruptcy or other insolvency proceedings are instituted against us or that we seek to revoke or challenge the validity of any licensed patents. If, for any reason, the Bayer License Agreement is terminated or we otherwise lose important rights, it would have a significant and adverse effect on our business and our ability to develop and commercialize our current product candidates, raise capital, or continue our operations.

The Bayer License Agreement imposes on us obligations relating to development, commercialization, funding, payment, diligence, intellectual property protection and other matters. We paid Bayer an upfront license fee of $5.0 million following the closing of the Business Combination. In addition, we are obligated to make significant future payments to Bayer upon the achievement of certain development and commercial sales milestones involving licensed products. The size and timing of these milestone payments will vary greatly depending on factors such as the particular licensed product, whether it involves a P-TEFb licensed product or a bioconjugation licensed product (and which bioconjugation program), the number of distinct disease indications, the number of different countries with respect to which the milestone is achieved and the level of net commercial sales, and it is therefore difficult to estimate the total payments that could become payable to Bayer and when those payments would be due. If we were to achieve all of the milestones for each of the countries and disease indications, we would be obligated to pay development and commercial milestone payments that range from $110.0 million to up to $318.0 million per licensed product, and upon successful commercialization of at least five licensed products, we could be required to pay aggregate milestone payments in excess of $1.0 billion. In addition to milestone payments, we are also required to pay Bayer under the Bayer License Agreement ongoing royalties in the single digit to low double-digit percentage range on net commercial sales of licensed products.

To the extent we are able to achieve any of these milestones, many of them would be achieved, and the related milestone payments owed, before we are able to generate sufficient revenues (or any revenues in the case of development milestones). Accordingly, we will need to obtain substantial additional funding, or enter into strategic alliances in order to pay these milestones, and there can be no assurance that we will be able to obtain the necessary funding on acceptable terms or at all or that we will be able to enter into strategic alliances at levels sufficient to pay these milestones or at all. If we are unable to raise the necessary additional funding, enter into the necessary strategic alliances, or otherwise pay these milestones, we would be in breach of the Bayer License Agreement, which if not cured would give Bayer the right to terminate the agreement or seek other remedies, which would have a significant and adverse effect on our business and our ability to develop and commercialize our current product candidates, raise capital, or continue our operations.

Our preclinical development, clinical trials, manufacturing, supply chains, and other operations and business activities, and the operations and business activities of third parties with whom we conduct business, including our contract manufacturers, contract research organizations, shippers, clinical trial sites, and

others, have been, and could continue to be, adversely affected by the effects of health pandemics and epidemics, including COVID-19.

Our business has been, and could continue to be, adversely affected by health pandemics and epidemics, including COVID-19, wherever we have clinical trial sites or other business operations. In addition, health pandemics and epidemics could cause significant disruption in the operations of third-party manufacturers, contract research organizations, shippers, clinical trial sites, and other third parties upon whom we rely. For example, COVID-19 presented a substantial public health and economic challenge around the world and affected, and could continue to affect, employees, patients, communities, and business operations, as well as the U.S. economy and financial markets. Many geographic regions, including those in which we and the third parties on whom we rely conduct operations, imposed, and in the future could again impose, "shelter-in-place," quarantines, or similar orders or restrictions to control the spread of COVID-19. These measures negatively impacted our productivity, disrupted our business, delayed our preclinical and clinical programs and timelines and limited our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations, now or in the future, could negatively impact our business, operating results, and financial condition.

We are dependent on a worldwide supply chain for products to be used in our clinical trials and, if approved by the regulatory authorities, for commercialization. Quarantines, shelter-in-place, and similar government orders and restrictions, staffing shortages, and other disruptions in operations, whether related to COVID-19 or other health pandemics or epidemics, have impacted, and could continue to impact, personnel at third-party manufacturing facilities in the United States and other countries, or the availability or cost of materials, which has impacted, and could continue to impact, our supply chain. For example, any manufacturing supply interruption of any product candidate could adversely affect our ability to conduct ongoing and future clinical trials of such product candidate. In addition, delays, closures, and other disruptions of transportation carriers and modal hubs could materially impact our clinical development and any future commercialization timelines.

If our relationships with our suppliers or other vendors are delayed, scaled back or terminated as a result of health pandemics or epidemics, including COVID-19, we may not be able to enter into arrangements with alternative suppliers or vendors or do so on commercially reasonable terms or in a timely manner. Switching or adding additional suppliers or vendors involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new supplier or vendor commences work. As a result, delays could generally occur, which could adversely impact our ability to meet our desired clinical development and any future commercialization timelines. See "Risks Related to Our Dependence on Third Parties."

In addition, our clinical trials have been, and could continue to be, affected by COVID-19 or future health pandemics or epidemics. Clinical site initiation and patient enrollment have been, and could continue to be, delayed due to staffing shortages, prioritization of hospital resources toward the treatment and management of patients impacted by pandemics or epidemics, concerns among patients about participating in clinical trials during a pandemic or epidemic, or public health measures imposed by governmental authorities in the countries and regions in which the clinical sites are located. Some patients may have difficulty following certain aspects of clinical trial protocols if quarantines or other restrictive measures impede patient movement or interrupt healthcare services. Similarly, our inability to successfully recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure or experience additional restrictions by their institutions, city, or state governments could adversely impact our clinical trial operations.

We are substantially dependent on the success of enitociclib, VIP236, and VIP943, our lead product candidates. If we are unable to complete development of, obtain approval for, and commercialize these lead product candidates in a timely manner, our business will be harmed.

Our future success is substantially dependent on our ability to timely commence and complete clinical trials, obtain marketing approval for, and successfully commercialize enitociclib, VIP236, and VIP943, our lead

product candidates. We are investing significant efforts and financial resources in the research and development of these lead product candidates, which will require additional clinical development, evaluation of clinical, preclinical, and manufacturing activities, 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 these or any other product candidates before we receive marketing approval from the FDA and comparable foreign regulatory authorities, and we may never receive such marketing approvals.

The success of these lead product candidates will depend on several factors, including the following:

- the initiation, successful patient enrollment, and timely completion of clinical trials;
- establishing and maintaining relationships with contract research organizations and clinical sites for clinical development in the United States and internationally;
- the frequency and severity of adverse events in the clinical trials and additional drug-related adverse events;
- achieving dose selection, efficacy, safety, and tolerability profiles that are satisfactory to the FDA or any comparable foreign regulatory authority for marketing approval;
- establishing and maintaining supply arrangements with third party drug product suppliers, manufacturers, and distributors;
- obtaining and maintaining patent protection, trade secret protection, and regulatory exclusivity, both in the United States and internationally;
- a continued acceptable safety profile following any marketing approval; and
- our ability to compete with other therapies.

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

We are at an early stage in development efforts for our product candidates, and we may not be able to successfully develop, manufacture, complete clinical trials and commercialize our product candidates on a timely basis or at all.

Enitociclib is a novel P-TEFb/CDK9 inhibitor and its potential therapeutic benefit is unproven. While several CDK9 inhibitor candidates are under development by other companies, there is currently no approved therapy inhibiting CDK9 for the treatment of cancers, and as a result, the regulatory pathway for enitociclib may present novel issues that could cause delays in development or approval. While results from preclinical data and early clinical trials of enitociclib have shown tolerable side effects and a reduction in MCL1 and MYC mRNA, enitociclib may not demonstrate in patients any or all of the pharmacological benefits we believe it may possess. We have not yet succeeded and may never succeed in demonstrating efficacy and safety for enitociclib in pivotal clinical trials or in obtaining marketing approval thereafter. Positive results from preclinical studies or early-stage clinical trials are not necessarily predictive of the results of planned clinical trials of enitociclib. If we cannot replicate the positive results from Bayer's Phase 1 clinical trials in our clinical trials, we may be unable to successfully develop, obtain regulatory approval for, and commercialize enitociclib, which could materially harm our business.

VIP943, VIP924, and VIP236 are part of a novel bioconjugation platform, and their potential therapeutic benefits are unproven, and we may never develop, successfully conduct, obtain marketing approval, and

commercialize any of the product candidates in our bioconjugation platform. While several bioconjugation and ADC candidates are under development by other companies, there is currently no approved bioconjugation therapy using our proprietary cytotoxin (an optimized CPT payload derived from SN38, a well-known cytotoxic drug and active metabolite of irinotecan) or an ADC using KSPi and CellTrapper. We may uncover a previously unknown risk associated with KSPi or our optimized CPT payload, our CellTrapper technology may not be as impermeable as initial testing suggest, our linker technology may not be as effective as initial testing suggests, or other issues that may be more problematic than we currently believe, which may prolong the period of observation required for obtaining, or result in the failure to obtain, regulatory approval or may necessitate additional preclinical and clinical testing. While results from preclinical trials of VIP943, VIP924, and VIP236 in mouse xenograft models have shown proof-of-concept for each, VIP943, VIP924, and VIP236 may not demonstrate in patients any or all of the pharmacological benefits we believe they may possess. If the KSPi warhead or optimized CPT payload that we use is not safe in certain product candidates, we would be required to abandon or redesign all of our current lead ADC or SMDC product candidates. We have not yet succeeded and may never succeed in demonstrating efficacy and safety of VIP943, VIP924, and VIP236 in pivotal clinical trials or in obtaining marketing approval thereafter. Positive results from preclinical trials are not necessarily predictive of the results of planned clinical trials of VIP943, VIP924, and VIP236.

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

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

The success of 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;
- obtaining regulatory permission to initiate clinical trials;
- contracting with the necessary parties to conduct clinical trials;
- successful enrollment of patients in, and the completion of, clinical trials on a timely basis;
- the timely manufacture of sufficient quantities of the product candidate for use in clinical trials; and
- adverse events in the clinical trials.

Results from early-stage clinical trials may not be predictive of results from late-stage or other clinical trials.

Positive and promising results from preclinical studies and early-stage clinical trials may not be predictive of results from late-stage clinical trials or from clinical trials of the same product candidates for the treatment of other indications. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Late-stage clinical trials could differ in significant ways from early-stage clinical trials, including changes to inclusion and exclusion criteria, efficacy endpoints, dosing regimen, and statistical design. Moreover, success in clinical trials in a particular indication does not guarantee that a product candidate will be successful for the treatment of other indications. Many companies in the biotechnology industry have suffered significant setbacks in late-stage

clinical trials after achieving encouraging or positive results in early-stage development. There can be no assurance that we will not face similar setbacks in our ongoing or planned late-stage clinical trials and any subsequent or post-marketing confirmatory clinical trials. Therefore, despite positive results observed in early-stage clinical trials, our product candidates may fail to demonstrate sufficient efficacy in our pivotal or post-marketing confirmatory clinical trials.

We rely in part on the clinical trial data provided by Bayer in assessing the viability of enitociclib, and such clinical trial data has not been verified by us or any independent third parties.

Our present development involving enitociclib relies in part upon previous clinical trials conducted by Bayer or other third parties over whom we had no control and before we in-licensed enitociclib. We are relying on the results of unaudited clinical trial data from investigator reports that are subject to change. As is typical for Phase 1 studies, such as enitociclib, no independent review committee has reviewed the data. Furthermore, if we are unable to replicate the results from Bayer's clinical trials in our clinical trials, we may be unable to successfully develop, obtain regulatory approval for, and commercialize enitociclib. Although we are not currently aware of any such problems, any problems that emerge with clinical development conducted prior to our in-licensing may affect future results or our ability to document prior development and to conduct clinical trials, which could delay, limit, increase the cost of, or prevent regulatory approval for enitociclib.

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 publish preliminary interim or "top-line" data from clinical trials. Positive preliminary data may not be predictive of such trial's subsequent or overall results. Preliminary data are subject to the risk that one or more of the outcomes may materially change as more data become available. Additionally, preliminary data 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. Therefore, positive preliminary results in any ongoing clinical trial may not be predictive of such results in the completed trial. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully evaluate all data. As a result, preliminary data that we report may differ from future results from the same clinical trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Preliminary data also remains 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, preliminary data should be viewed with caution until the final data are available. Material adverse changes in the final data compared to preliminary data could materially harm our business and prospects.

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

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

- timing of market introduction, number, clinical profile, and potential advantages of competitive drugs;
- our ability to provide acceptable evidence of safety and efficacy;
- changing standards of medical care;
- relative convenience and ease of administration;

- restrictions on the use of our product candidates, 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;
- pricing and cost-effectiveness, which may be subject to regulatory control;
- availability of coverage, reimbursement and adequate payment from health maintenance organizations and other third-party payors; and
- prevalence and severity of adverse side effects.

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

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

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

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

Our competitors are developing a large number of drug candidates for the treatment of solid tumors, leukemia, B-cell malignancies, lymphomas, myelodysplastic syndrome, and other conditions. Any product candidates that we successfully develop and commercialize will compete with these drug candidates, 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. Several pharmaceutical and biotechnology companies have CDK9 inhibitors, ADCs, immunotherapies, or other products on the market or in clinical trials which may be competitive to our product candidates in oncology indications.

Our competitors, either alone or together with collaborators, may have significantly greater financial, manufacturing, marketing, drug development, technical and human resources, and commercial expertise than we do and may have begun developing their drug candidates earlier than us. Our competitors may also have more experience:

- developing drug candidates;
- conducting preclinical and clinical trials;
- obtaining regulatory approvals; and
- commercializing product candidates.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe adverse effects, are more convenient, have a

broader label, are marketed more effectively, are reimbursed, or are less expensive than any products that we may develop. Our competitors also may obtain marketing approval from the FDA or other comparable foreign regulatory authorities for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive, or not economical. We anticipate that we will face increased competition in the future as new companies enter the markets and as scientific developments progress. 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.

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

Because we have limited financial and managerial resources, we focus on development programs, therapeutic platforms and product candidates that we identify for specific indications. As a result, we may forego or delay the pursuit of opportunities with other therapeutic platforms or product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs, therapeutic platforms, and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing, or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights. For example, currently we are only developing a limited number of product candidates that we acquired rights to develop under the Bayer License Agreement and the product candidates we are developing may never be commercially viable, whereas product candidates that we chose not to develop may be more commercially viable.

Clinical trials are expensive, time consuming, subject to enrollment and other delays, and may be required to continue beyond our available funding, and we cannot be certain that we will be able to raise sufficient funds to successfully complete the development, clinical trials and commercialization of any of our product candidates currently in preclinical and clinical development, should they succeed.

Clinical trials have uncertain outcomes and may be required to continue beyond our available funding. Failure can occur at any stage of the clinical trials, and we may experience numerous unforeseen events that could delay or prevent commercialization of our current or future product candidates, including, but not limited to:

- delays in securing clinical investigators and trial sites for our clinical trials;
- delays in obtaining Institutional Review Board, and regulatory approvals to commence a clinical trial;
- slower than anticipated rates of patient recruitment and enrollment, or not reaching the targeted number of patients, because of factors such as competition for patients from other trials, difficulty identifying patients with our proposed indications, the impact of COVID-19 or other health pandemics or epidemics, or limited or no availability of coverage, reimbursement, or adequate payment from health maintenance organizations and other third-party payors;
- unforeseen safety issues;
- uncertain dosing issues that could arise as a result of incompletely explored pharmacokinetic and pharmacodynamics behaviors or initiatives such as the FDA's Project Optimus;
- approval and introduction of new therapies or changes in standards of practice or regulatory guidance that render our clinical trial endpoints or the targeting of our proposed indications less attractive;

- inability to monitor patients adequately during or after treatment or problems with investigator or patient compliance with the trial protocols;
- inability to replicate in large controlled studies safety and efficacy data obtained from a limited number of patients in uncontrolled trials;
- inability or unwillingness of medical investigators to follow our clinical protocols; and
- unavailability of clinical trial supplies.

In addition, we had no involvement with or control over the preclinical or clinical development of our product candidates prior to their in-license from Bayer. We are dependent on Bayer having conducted such development in accordance with the applicable protocols and legal, regulatory and scientific standards, having accurately reported the results of all preclinical studies and clinical trials and other research they conducted prior to our acquisition of the rights to our product candidates, having correctly collected and interpreted the data from these studies, trials and other research, and having supplied us with complete information, data sets and reports required to adequately demonstrate the results reported through the date of our acquisition of these product candidates. Problems in any of these areas could result in increased costs and delays in the development of our product candidates, which could adversely affect our ability to generate any future revenue from sales of our product candidates, if approved.

If we suffer significant delays, setbacks or negative results in, or termination of, our clinical trials, we may be unable to continue development of our product candidates or generate revenue, and our development costs could increase significantly. Adverse or inconclusive results from our clinical trials may substantially delay, or halt entirely, any further development of our product candidates.

Adverse or inconclusive results from our clinical trials may substantially delay, or halt entirely, any further development of our product candidates. Many companies have failed to demonstrate the safety or effectiveness of product candidates in later stage clinical trials notwithstanding favorable results in early stage clinical trials. Previously unforeseen and unacceptable side effects could interrupt, delay, or halt clinical trials of our product candidates and could result in the FDA denying approval of our product candidates. We will need to demonstrate safety and efficacy for specific indications of use, and monitor safety and compliance with clinical trial protocols and other good clinical practice requirements, throughout the development process. To date, long-term safety and efficacy has not been demonstrated in clinical trials for any of our product candidates.

Certain toxicity and adverse events have been noted in some of the preclinical and clinical trials involving certain of our product candidates. For example, neutropenia was observed in some patients receiving enitociclib. In addition, we have or may pursue clinical trials for more than one indication, and there is a risk that unacceptable toxicity or adverse events observed in a trial for one indication could result in the delay or suspension of all trials involving the same product candidate. Even if we believe that the data collected from clinical trials of our product candidates are promising with respect to safety and efficacy, such data may not be deemed sufficient by regulatory authorities to warrant product approval. Regulatory officials could interpret such data in different ways than we do, which could delay, limit, or prevent regulatory approval. The FDA or we may suspend or terminate clinical trials at any time. Any failure or significant delay in completing clinical trials for our product candidates, or in receiving regulatory approval for the commercialization of our product candidates, may materially harm our business and reputation.

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 prospects.

Our business exposes us to significant product liability risks inherent in the development, testing, manufacturing, and marketing of therapeutic treatments. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in an

FDA or other regulatory authority investigation of the safety and efficacy of our products, our manufacturing processes and facilities, or our marketing programs. FDA or other regulatory authority investigations could potentially lead to a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used, or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our products, injury to our reputation, costs to defend the related litigation, a diversion of management's time and our resources, and substantial monetary awards to clinical trial participants or patients. 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 and difficult to obtain. 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. In addition, any inability or delay in obtaining such insurance could negatively impact our ability to conduct clinical trials on a timely basis or at all.

Any product candidates we develop may become subject to unfavorable third-party coverage and reimbursement practices, as well as drug pricing regulations, including those under the Inflation Reduction Act of 2022.

In domestic and foreign markets, sales of any of our product candidates, if approved, will depend, in part, on the extent to which the costs of our products will be covered by third-party payors, such as government health programs, commercial insurance, and managed healthcare organizations. These third-party payors decide which drugs will be covered and establish reimbursement levels for those drugs. The containment of healthcare costs has become a priority of governments as well as private third-party payors, and the prices of drugs have been a focus in this effort, including the drug pricing provisions under the Inflation Reduction Act of 2022. Governments and private third-party payors have attempted to control costs by subjecting certain drugs to mandatory price negotiations and limiting coverage and the amount of reimbursement for certain medications, which could affect our ability to sell our product candidates profitably. Cost-control initiatives could cause us to decrease the price we might establish for products, which could result in lower than anticipated product revenues. Adverse pricing limitations may hinder our ability to recoup our investment in our current or future product candidates, even if such product candidates obtain marketing approval.

Reimbursement by a third-party payor may depend upon several factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective, and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time consuming and costly process that could require us to provide supporting scientific, clinical, and cost-effectiveness data for the use of our products to the payor. Further, there is significant uncertainty related to third-party payor coverage and reimbursement of newly approved drugs. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. We cannot be sure that coverage or adequate reimbursement will be available for any of our product candidates. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our products. If reimbursement is not available or is available only to limited levels, we may not be able to commercialize certain of our products. In addition, in the United States, third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of new drugs. As a result, significant uncertainty exists as to whether and how much third-party payors will reimburse patients for their use of newly approved drugs, which in turn will put pressure on the pricing of drugs.

We are making use of biomarkers in certain instances, which are not scientifically validated, and our reliance on biomarker data may thus cause us to direct our resources inefficiently.

We are making use of biomarkers in certain instances to facilitate our drug development and to optimize our clinical trials. Biomarkers are proteins or other substances whose presence in the blood or tumor cells can serve as an indicator of specific cell processes. We believe that these biomarkers serve a useful purpose in helping us to evaluate whether our product candidates are having their intended effects through their assumed mechanisms and that they may thus enable us to identify more promising product candidates at an early stage and direct our resources efficiently. We also believe that biomarkers may eventually allow us to improve patient selection in connection with clinical trials and monitor patient compliance with trial protocols.

For most purposes, however, biomarkers have not been scientifically validated. If our understanding and use of biomarkers is inaccurate or flawed, or if our reliance on them is otherwise misplaced, we will not only fail to realize any benefits from using biomarkers but may also be led to invest time and financial resources inefficiently in attempting to develop less promising product candidates. Moreover, biomarker data are not currently accepted by the FDA or other regulatory agencies in the United States, the European Union or elsewhere in applications for regulatory approval of product candidates, and there is no guarantee that such data will ever be accepted by the relevant authorities. Our biomarker data should not be interpreted as evidence of efficacy.

As we evolve from a company primarily involved in discovery and development to one also involved in the commercialization of drugs, we may encounter difficulties in managing our growth and expanding our operations successfully.

To execute our business strategy, we will need to expand our development, control, and regulatory capabilities and develop financial, manufacturing, marketing, and sales capabilities or contract with third parties to provide these capabilities for us. If our operations expand, we expect that we will need to manage additional relationships with various collaborative partners, suppliers, and other third parties. Our ability to manage our operations and any growth will require us to make appropriate changes and upgrades, as necessary, to our operational, financial, and management controls, reporting systems, and procedures wherever we may operate. Any inability to manage growth could delay the execution of our business plan or disrupt our operations.

Our founders' success in developing cancer therapies while at other companies does not guarantee that we will be successful in developing or commercializing any of our current or future product candidates.

Drs. Ahmed M. Hamdy and Raquel E. Izumi were the principal co-founders of Acerta Pharma BV, the company that developed CALQUENCE® and was eventually acquired by AstraZeneca. Drs. Hamdy and Izumi's prior success in licensing a preclinical stage molecule and developing that molecule through clinical trials and to full marketing approval does not guarantee that we will successfully develop or commercialize any of our current or future product candidates. As such, we make no assurance that Drs. Hamdy and Izumi's past success with Acerta Pharma is indicative of our success or ability to develop and commercialize any of our current or future product candidates.

In June 2022, we implemented certain workforce and cost reduction measures in connection with our strategic plan, and there can be no assurance that such measures will not adversely affect our business.

In June 2022, our board of directors approved a strategic plan to prioritize and focus our resources on our ongoing enitociclib clinical studies for double-hit DLBCL, Richter syndrome and CLL and our next generation bioconjugation platform and streamline and realign our resources to support these prioritized studies and programs. This plan included a reduction in our full-time employees by 33% and other cost reduction measures. There can be no assurance that these workforce and cost reduction measures will not delay or otherwise negatively impact the execution of our business plan or disrupt our operations, which would adversely affect our business and our ability to achieve our business objectives.

The failure to attract and retain skilled personnel and key relationships could impair our drug development and commercialization efforts.

Our business is highly dependent on our ability to attract and retain executive management, clinical development, scientific, technical, and other skilled personnel. There is currently intense competition for executives and employees with these skills and expertise, and this competition is likely to continue. The inability to attract and retain our management, clinical development, scientific, research, technical, and other skilled personnel may delay or prevent the achievement of our drug development and other business objectives and could have a material adverse effect on our business. We also rely on consultants and advisors to assist us in formulating and implementing our business objectives. Our consultants and advisors are either self-employed or employed by other organizations, and they may have conflicts of interest or other commitments, such as consulting or advisory contracts with other organizations, that may affect their ability to contribute to our business and operations.

We or the third parties upon whom we depend may be adversely affected by natural disasters, health epidemics, and other natural or man-made accidents or incidents, including the impact of climate change, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Any unplanned event, such as a flood, fire, explosion, earthquake, extreme weather condition, health pandemic or epidemic (such as COVID-19), power shortage, telecommunication failure, war (such as the war in Ukraine), or other natural or man-made accidents or incidents, including the impact of climate change, that result in us being unable to fully use our facilities, or those of our third party contract manufacturers, or conduct our preclinical studies or clinical trials, may have a material and adverse effect on our business. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates, or the interruption of our business operations.

The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. 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, there can be no assurance that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our third-party contract manufacturers, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs and commercialization efforts may be harmed.

Our business and operations would be adversely affected in the event that our computer systems or those of our partners, contract research organizations, contractors, consultants, or other third parties we work with were to suffer system failures, cyberattacks, loss of data, or other security incidents, or we fail to comply with applicable data security and privacy laws, regulations, and standards.

Despite the implementation of security measures, our computer systems, as well as those of our partners, contract research organizations, IT service providers, contractors, consultants, law and accounting firms, and other third parties we work with, may sustain damage from computer viruses, unauthorized access, data breaches, phishing attacks, ransomware attacks, denial-of-service attacks, cybercriminals, natural disasters, terrorism, war, and telecommunication and electrical failures. We rely on our partners and third-party providers to implement effective security measures and identify and correct for any such failures, deficiencies, or breaches. The risks of a security breach or disruption, particularly through cyberattacks or cyber intrusion, including by computer hackers, foreign governments, and cyber-terrorists, have increased significantly and are becoming increasingly difficult to detect. If a failure, accident, or security breach were to occur and cause interruptions in our operations, or the operations of our partners or third-party providers, it could result in a misappropriation of confidential information, including our intellectual property or financial information or clinical trial participant personal data, a material disruption or delay in our drug development programs, and significant monetary losses. For example, the loss of preclinical or clinical trial data from completed, ongoing, or planned trials, or chemistry,

manufacturing, and controls data for our product candidates, could result in delays in regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

In addition, we must comply with increasingly complex, rigorous, and sometimes conflicting laws, regulations, and standards enacted to protect business and personal data in the United States, Europe, and elsewhere. For example, the European Union has adopted the General Data Protection Regulation (the "GDPR"), the United Kingdom has adopted the Data Protection Act 2018 (as updated), and California has adopted the California Consumer Privacy Act (the "CCPA"). These laws impose additional obligations on companies regarding the handling of personal data and provide certain individual privacy rights to persons whose data is stored. Compliance with existing, proposed, and recently enacted laws, regulations, and standards (including implementation of the privacy and process enhancements called for under GDPR and CCPA) can be costly and time consuming, and any failure to comply with these laws, regulations, and standards could subject us to legal and reputational risks. Misuse of or failure to secure personal information, including any breach, loss, or compromise of clinical trial participant personal data, could also result in violation of data privacy laws, regulations, and standards against the Company by governmental entities or others, imposition of fines by governmental authorities, and damage to our reputation and credibility, and could have a negative impact on our business.

Risks Related to Our Financial Position and Need for Additional Capital

We are at an early stage of development as a company and our limited operating history may make it difficult to evaluate our ability to succeed.

We were incorporated in March 2019, and our operations to date have been largely focused on licensing our product candidates, raising capital, building our management team and infrastructure and conducting preclinical studies and early clinical trials. We have not yet demonstrated an ability to obtain regulatory approvals, manufacture products on a commercial scale, or partner with contract manufacturing organizations to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing products. Moreover, we will need to eventually transition from a company with a development focus to a company capable of undertaking commercial activities. We may encounter unforeseen expenses, difficulties, complications, and delays, and may not be successful in such a transition.

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

We have incurred net losses in each reporting period since our inception, have not generated any revenue from product sales to date and have financed our operations principally through the sale of our equity securities. Our losses have resulted principally from expenses incurred in connection with licensing our product candidates from Bayer, raising capital, building our management team and business infrastructure, and conducting preclinical studies and early clinical trials. As a result, we expect that it will be several years, if ever, before we have a commercialized product and are able to generate revenue from product sales. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future as we continue our research and development efforts and seek to obtain regulatory approval and commercialization of our product candidates. Even if we succeed in receiving marketing approval for and commercializing one or more of our product candidates, we expect that we will continue to incur substantial research and development and other expenses as we discover, develop, and market additional potential products. 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, need to raise additional capital, and ability to achieve and maintain profitability.

We require substantial 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, or eliminate one or more of our research and drug development programs or future commercialization efforts.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive, and uncertain process that takes years to complete. We expect our expenses to substantially increase in connection with our ongoing activities, particularly as we initiate and conduct clinical trials of, and seek marketing approval for, enitociclib, VIP236, VIP943, VIP924, and our other product candidates. Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. These expenditures will include payments associated with the Bayer License Agreement and development and commercial milestones, in each case prior to generating any product sales. Additionally, following commencement of any commercial sales of our licensed products, we will be responsible for significant further payments upon the achievement of certain sales milestones and tiered royalty payments on net commercial sales.

Our expenses could increase beyond expectations if we are required by the FDA 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, we expect to incur significant commercialization expenses related to drug 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 amounts necessary to successfully complete the development and commercialization of any product candidate we develop. We also incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to maintain our continuing operations.

As of December 31, 2022, we had approximately $52.5 million in cash, cash equivalents, and marketable securities. We intend to use our existing capital resources to advance and expand our preclinical and clinical programs, to fund certain of the milestone payments under the Bayer License Agreement and our public company compliance costs, and for working capital and other general corporate purposes. Based on current business plans and assumptions, we believe that our existing cash, cash equivalents, and marketable securities will be sufficient to fund our operating expenses and capital expenditure requirements into late 2024. Our estimate as to how long we expect our existing cash to be able to continue to fund our operating expenses and capital expenditure requirements is based on plans and assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could result in less cash available to us or cause us to consume capital significantly faster than we currently anticipate, and we may need or choose to seek additional funds sooner than planned.

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. Raising additional funds by issuing equity or convertible debt securities may cause our stockholders to experience substantial dilution. Raising additional funds through debt financing may involve covenants that restrict our business activities and options. To the extent that we raise additional funds through collaborations and licensing arrangements, we may have to relinquish valuable rights to our drug discovery and other technologies, development programs, or product candidates, or grant licenses on terms that may not be favorable to us. Additional funding may not be available to us on favorable terms, or at all, particularly in light of the current economic and market conditions. We do not have any committed external source of funds. Market volatility resulting from COVID-19, inflation and other economic and market conditions, the war in Ukraine, or other factors could also adversely impact our ability to access capital as and when needed. 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 preclinical programs, clinical trials, or future commercialization efforts.

The Bayer License Agreement obligates us to make significant milestone and royalty payments, some of which will be triggered prior to the commercialization of any of our other product candidates.

We will be responsible for significant future contingent payments and royalties under the Bayer License Agreement upon the achievement of certain development, regulatory, and sales milestone events, some of which may occur prior to commercialization of any of our product candidates. In such event, we would be required to make certain of these payments prior to the time at which we are able to generate sufficient revenue, if any, from commercial sales of any of our product candidates. There can be no assurance that we will have the funds necessary to make such payments, be able to obtain the necessary funding on acceptable terms or at all, or enter into strategic alliances at levels sufficient to pay these milestones or at all. If we are unable to raise the necessary additional funding, enter into the necessary strategic alliances, or otherwise pay these milestones, we would be in breach of the Bayer License Agreement, which if not cured would give Bayer the right to terminate the agreement or seek other remedies, which would have a significant and adverse effect on our business and our ability to develop and commercialize our current product candidates, raise capital, or continue our operations

We may never achieve or sustain profitability.

We do not know when or whether we will become profitable. To date, we have not commercialized any products or generated any revenues from the sale of products. We do not expect to generate any product revenues in the near term. To become and remain profitable, we must succeed in developing, obtaining regulatory approval for and commercializing one or more of our product candidates. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our product candidates, discovering and developing additional product candidates, obtaining regulatory approval for any product candidates that successfully complete clinical trials, establishing commercialization capabilities for any approved products, and achieving market acceptance for any approved products. We may never succeed in these activities. Even if we succeed in these activities, we may never generate revenue in an amount sufficient to achieve profitability.

Because of the numerous risks and uncertainties associated with biotechnology product development and commercialization, we are unable to accurately predict whether and when we will achieve profitability. If we are required by the FDA or any comparable regulatory authority in other jurisdictions to perform preclinical studies or clinical trials in addition to those we currently expect to conduct, or if there are any delays or complications in completing preclinical studies of our product candidates or, if preclinical studies are successful, in submitting an IND application, a BLA or an NDA to the FDA, manufacturing clinical trial supplies, and completing clinical trials for our product candidates, our expenses could increase substantially and our ability to achieve profitability could be further delayed. As we obtain certain developmental, regulatory, and sales milestones, we will be responsible for contingent milestone payments and royalties to Bayer under the Bayer License Agreement.

Even if we achieve profitability, we may not be able to sustain profitability in subsequent periods. After we achieve profitability, if ever, we expect to continue to engage in substantial research and development activities and to incur substantial expenses to develop and commercialize additional product candidates. In addition, we may encounter unforeseen expenses, difficulties, complications, delays, and other unknown factors that may adversely affect our revenues, expenses, and profitability. Our failure to achieve or sustain profitability would depress the market value of our common stock and could impair our ability to execute our business plan, raise capital, develop additional product candidates, or continue our operations.

Risks Related to Regulatory Approval and Other Legal Compliance Matters

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

Our product candidates are subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, safety, dose selection, efficacy, approval, recordkeeping,

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

We have not conducted, managed, or completed large-scale or pivotal clinical trials nor managed the regulatory approval process with the FDA or any other regulatory authority with respect to our product candidates. 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, changes in policy, or new initiatives during the period of drug development, clinical trials, and FDA regulatory review. For example, in the U.S., the FDA's Project Optimus initiative will transform the dose-finding and dose optimization paradigm across oncology to emphasize selection of a dose or doses that maximizes not only the efficacy of a drug but the safety and tolerability as well, which could increase the development time and costs of our clinical trials. In addition, the European Union began transitioning to full implementation of the EU Clinical Trials Regulation in January 2022, and the United Kingdom's Medicines and Healthcare products Regulatory Agency has begun to transition the U.K. to a fully independent clinical trial regulatory framework following Brexit, both of which could result in significant uncertainties and delays.

Any delay or failure in seeking or obtaining required approvals for a product candidate would have a material and adverse effect on our ability to generate revenue from such product candidate. Furthermore, any regulatory approval to market a product candidate may be subject to significant limitations on the approved uses or indications for which we may market the product candidate or the labeling or other restrictions. In addition, the FDA has the authority to require a Risk Evaluation and Mitigation Strategy as part of approving an NDA or BLA, or after approval, which may impose further requirements or restrictions on the distribution or use of an approved product candidate. 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 a product candidate 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 most if not all of the risks associated with FDA approval 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. Any delay or failure in obtaining foreign regulatory approval for a product candidate would have a material and adverse effect on our ability to generate revenue from such product candidate in that foreign jurisdiction.

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

If our product candidates are associated with a high and unacceptable severity and prevalence of side effects or 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 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. Such results could result in a more restrictive label, implementation of a Risk Evaluation and Mitigation Strategy, or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. 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 could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities and may prevent us from achieving or maintaining market acceptance of the affected product candidate, which could harm our business and prospects.

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

If significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to the clinical trials, patients may drop out of our clinical trials, or we may be required to abandon the clinical trials or our development efforts of that product candidate altogether. We, the FDA, or other comparable regulatory authorities or an Institutional Review Board 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 and prospects.

Further, if any of our product candidates obtains marketing approval, toxicities associated with such product candidates that were not seen during clinical trials 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, implementation of a Risk Evaluation and Mitigation Strategy, 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.

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

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing, promotion, and reimbursement of the product candidate in those jurisdictions. 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 jurisdictions. If we fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced, and our ability to realize the full market potential of our product candidates will be harmed.

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

Any regulatory approvals that we may receive for our product candidates will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the product candidate, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions, or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a Risk Evaluation and Mitigation Strategy 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, and on-going compliance with cGMP requirements and good clinical practices for any clinical trials that we conduct post-approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and standards. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility, or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. In addition, failure to comply with FDA and other comparable foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions, including:

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

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

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit, or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislative, administrative, or executive action, either in the United States or abroad. Such actions could impact our business and industry, including by imposing significant burdens on, or otherwise materially delaying, the FDA's and other regulatory authorities' ability to engage in regulatory and oversight activities. If these actions impose constraints on the ability of the FDA or other regulatory authorities to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

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

We may choose to seek an accelerated approval for one or more of our product candidates. Under the accelerated approval program, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. If such post-approval studies fail to confirm the drug's clinical benefit, the FDA may withdraw its approval of the drug.

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

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

We may also conduct international clinical trials. The acceptance of study data by the FDA, European Medicines Agency, 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 foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign-generated data alone unless (1) the data are applicable to the United States population and United States medical practice, (2) the clinical trials are performed by clinical investigators of recognized competence and pursuant to current good clinical practice requirements, and (3) the FDA is able to validate the data through an on-site inspection or other appropriate mean. Additionally, the FDA's clinical trial requirements, including the adequacy of the patient population studied and statistical powering, must be met. Such foreign clinical trials would also be subject to the applicable local laws of the foreign jurisdictions where the clinical trials are conducted. There can be no assurance that the FDA, European Medicines Agency, or any applicable foreign regulatory authority will accept data from clinical trials conducted outside of its applicable jurisdiction. If the FDA, European Medicines Agency, or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional clinical trials, which would be costly, time-consuming, and delay aspects of our business plan and may result in our product candidates not receiving approval for commercialization in the applicable jurisdiction.

The United Kingdom's withdrawal from the European Union imposes new regulatory costs and challenges that may have a negative effect on our business.

The United Kingdom left the European Union on January 31, 2020, an event commonly referred to as "Brexit," and following the "transition period," on December 30, 2020, the European Union, the European Atomic Energy Community, and the United Kingdom signed a Trade and Cooperation Agreement. Brexit imposes new regulatory costs and challenges that may have a material adverse effect on us and our operations. We may face decreased chances to obtain market approval for our products in the European Union, including the possibility that the European Medicines Agency will not accept data from our clinical trials conducted in the United Kingdom or will only do so if we comply with certain conditions. Conversely, since a significant proportion of the United Kingdom's regulatory framework affecting the pharmaceutical and biotechnological industry is derived from European Union directives and regulations, Brexit could materially alter the regulatory regime with respect to our product candidates in the United Kingdom, which may increase the time and costs associated with obtaining regulatory approval from the relevant authorities. It may also be time-consuming and expensive for us to alter our internal operations in order to comply with new regulations. Altered regulations could also add time and expense to the process by which our product candidates receive regulatory approval in the United Kingdom and the European Union.

In addition, following the Brexit vote, the European Union moved the European Medicines Agency's headquarters from the United Kingdom to the Netherlands. This transition may cause disruption in the administrative and medical scientific links between the European Medicines Agency and the UK Medicines and Healthcare products Regulatory Agency, including delays in granting clinical trial authorization or marketing authorization, disruption of import and export of active substance and other components of new drug formulations and disruption of the supply chain for clinical trial product and final authorized formulations. The United Kingdom's Medicines and Healthcare products Regulatory Agency has also begun to transition the U.K. to a fully independent clinical trial regulatory framework. The cumulative effects of the disruption to the regulatory framework may add considerably to the development lead time to marketing authorization and commercialization of products in the European Union and/or the United Kingdom.

We may be required to defend lawsuits or pay damages in connection with the alleged or actual violation of healthcare statutes such as fraud and abuse laws, and our corporate compliance programs can never guarantee that we are always in compliance with all relevant laws and regulations.

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal healthcare laws, commonly referred to as "fraud and abuse" laws, have been applied in recent years to restrict certain marketing practices in the pharmaceutical industry. Other jurisdictions, such as Europe, have similar laws. These laws include false claims and anti-kickback statutes. Anti-kickback laws make it illegal for a manufacturer to offer or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase of a product. The U.S. government has published many regulations relating to the anti-kickback statutes, including numerous safe harbors or exemptions for certain arrangements. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented, for payment to third-party payors including Medicare and Medicaid, claims for reimbursed products or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services.

Our activities relating to the sale and marketing of our products will be subject to scrutiny under these laws and regulations. It may be difficult to determine whether or not our activities comply with these complex legal requirements. Violations are punishable by significant criminal and/or civil fines and other penalties, as well as the possibility of exclusion of the product from coverage under governmental healthcare programs, including Medicare and Medicaid. If U.S. or foreign governments were to investigate or make allegations against us or any of our employees, or sanction or convict us or any of our employees, for violations of any of these legal requirements, this could have a material adverse effect on our business, including our stock price. Our activities could be subject to challenge for many reasons, including the broad scope and complexity of these laws and regulations, the difficulties in interpreting and applying these legal requirements, and the high degree of prosecutorial resources and attention being devoted to the biopharmaceutical industry and healthcare fraud by law enforcement authorities. During the last few years, numerous biopharmaceutical companies have paid multi-million dollar fines and entered into burdensome settlement agreements for alleged violation of these requirements, and other companies are under active investigation. Although we have developed and implemented corporate and field compliance programs, we cannot assure you that we or our employees, directors, or agents were, are, or will be in compliance with all laws and regulations or that we will not come under investigation, allegation, or sanction.

In addition, we may be required to prepare and report product pricing-related information to federal and state governmental authorities, such as the Department of Veterans Affairs and under the Medicaid program. The calculations used to generate the pricing-related information are complex and require the exercise of judgment. If we fail to accurately and timely report product pricing-related information or to comply with any of these or any other laws or regulations, various negative consequences could result, including criminal and/or civil prosecution, substantial criminal and/or civil penalties, exclusion of the approved product from coverage under governmental healthcare programs including Medicare and Medicaid, costly litigation, and restatement of our financial statements. In addition, our efforts to comply with this wide range of laws and regulations are, and will continue to be, time-consuming and expensive.

Our employees, agents, contractors, or collaborators may engage in misconduct or other improper activities.

We cannot ensure that our compliance controls, policies, and procedures will in every instance protect us from acts committed by our employees, agents, contractors, or collaborators, including, but not limited to, contract research organizations, electronic data capture companies, data management companies, contract clinical research associates, medical institutions, clinical investigators, contract laboratories, and other third parties to assist us in conducting clinical trials and obtaining regulatory approvals for our product candidates, that would violate the laws or regulations of the jurisdictions in which we operate, including, without limitation, healthcare, employment, foreign corrupt practices, environmental, competition, and patient and other privacy laws and

regulations. Misconduct by these parties could include intentional failures to comply with FDA or other applicable regulations, provide accurate information to the FDA and comparable regulatory authorities in other jurisdictions, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately, or disclose unauthorized activities to us.

Such misconduct also could involve the improper use of information obtained from clinical trials or interactions with the FDA or comparable regulatory authorities in other jurisdictions. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under these laws will increase significantly, and our costs associated with compliance with these laws are likely to increase. Such improper actions could subject us to civil or criminal investigations, and monetary and injunctive penalties, and could adversely impact our business and reputation.

In addition, we are subject to the Foreign Corrupt Practices Act and similar anti-bribery or anti-corruption laws, regulations, or rules of other countries in which we operate. The Foreign Corrupt Practices Act generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The Foreign Corrupt Practices Act also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the healthcare providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the Foreign Corrupt Practices Act. There is no certainty that our employees, agents, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. While we have implemented codes of conduct and other policies and controls to mitigate the risk of non-compliance with anti-corruption and anti-bribery laws, it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions stemming from a failure to comply with these laws or regulations. Violations of these laws and regulations could result in, among other things, administrative, civil, and criminal fines and sanctions against us, our officers, or our employees, the closing down of our facilities, requirements to obtain export licenses, exclusion from participation in federal healthcare programs including Medicare and Medicaid, implementation of compliance programs, integrity oversight and reporting obligations, 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 business, reputation, brand, international expansion efforts, and ability to attract and retain employees.

Risks Related to Our Dependence on Third Parties

Our applications for regulatory approval could be delayed or denied due to problems with studies conducted before we in-licensed the rights to some of our product candidates.

We currently license all of our product candidates from Bayer pursuant to the Bayer License Agreement. Our present development involving these product candidates relies to a significant extent upon previous development conducted by Bayer or other third parties over whom we had no control and before we in-licensed the product candidates. To receive regulatory approval of a product candidate, we must present all relevant data and information obtained during its development, including research conducted prior to our licensure of the product candidate. Although we are not currently aware of any such problems, any problems that emerge with preclinical or clinical development conducted prior to our in-licensing may affect future results or our ability to document prior development and to conduct clinical trials, which could delay, limit or prevent regulatory approval for our product candidates.

Our manufacturing processes are complex, and we have no manufacturing capability and will initially rely on third-party manufacturers for the development, clinical trials, and commercialization of any product candidate we may develop or sell.

The processes for manufacturing our product candidates, particularly our bioconjugation product candidates, are very complex and take significant time and resources to develop and implement. In addition, our supply chain of raw materials, consumables, intermediates, drug substances, and drug products for use in our clinical trials and, if approved by regulatory authorities, commercialization rely on a worldwide supply chain. We do not currently operate our own manufacturing facilities or have our own manufacturing capabilities for clinical or commercial production of our product candidates under development and intend to initially rely on third-party manufactures for any such manufacturing. Third-party manufacturers that have the capabilities, processes, and expertise that we need for our product candidates and that can meet our quality standards may be difficult to identify or retain, and even if retained, such third-party manufacturers may not be able to perform the manufacturing services we require within our planned timeframes. We anticipate relying on a limited number of third-party manufacturers until such time, if any, as we decide to expand our operations to include manufacturing capabilities.

If the FDA or comparable foreign regulatory authorities approve any of our product candidates for commercial sale, or if we significantly expand our clinical trials, we will need to manufacture them in larger quantities, and we may not be able to successfully increase the manufacturing capacity for any of our product candidates in a timely or economic manner, or at all. Until such time, if any, that we directly control the manufacturing of our product candidates, we will have limited control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance, and qualified personnel, and we will be dependent on our third-party manufacturing partners for compliance with current cGMP requirements for the manufacture of our product candidates. If our third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable foreign regulatory authorities, we will not be able to secure or maintain regulatory approval for our product candidates. In addition, if any third-party manufacturer makes improvements in the manufacturing process for our product candidates, we may not own, or may have to share, the intellectual property rights to such innovations.

Certain of our key third-party manufacturers are located in the European Union, which is now experiencing the direct impact of the war in Ukraine on supply chains and other economic matters, including inflation. Such third-party manufacturers may implement, and certain of such manufacturers have begun to implement, price increases that could negatively impact our ability to afford such manufacturing services. Any inability to identify and retain third-party manufacturers on a cost-effective basis, performance failure on the part of such manufacturers, or disruption in our supply chain as a result of political unrest, trade disputes, natural disasters, pandemics or epidemics, climate change, or otherwise, could delay our clinical trials and development, regulatory approval of our product candidates, commercialization of our product candidates, or our ability to sell our commercial products, resulting in additional losses and depriving us of potential product revenues.

If we fail to enter into and maintain successful collaborative arrangements or strategic alliances for our product candidates, we may have to reduce or delay our product candidate development or increase our expenditures.

An important element of our strategy for developing, manufacturing, and commercializing our product candidates is entering into collaborative arrangements or strategic alliances with pharmaceutical companies, research institutions, or other industry participants to advance our programs and enable us to maintain our financial and operational capacity. We face significant competition in seeking appropriate collaborations and alliances. We may not be able to negotiate such collaborations or alliances on acceptable terms, if at all. In addition, such collaborations or alliances may be unsuccessful. If we fail to create and maintain suitable collaborations or alliances, we may have to limit the size or scope of, or delay, one or more of our research or

development programs. In addition, these kinds of collaborative arrangements and strategic alliances may place certain aspects of the development of our product candidates outside of our control, may require us to relinquish important rights, or may otherwise be on terms unfavorable to us.

Dependence on collaborative arrangements or strategic alliances will subject us to several risks, including the risk that:

- we may not be able to control the amount and timing of resources that our collaborators may devote to the product candidates;
- our collaborators may experience financial difficulties;
- we may be required to relinquish important rights such as marketing and distribution rights;
- business combinations or significant changes in a collaborator's business strategy may adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement;
- a collaborator could independently move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and
- collaborative arrangements are often terminated or allowed to expire, which would delay development and may increase the cost of developing our product candidates.

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

As product candidates proceed through preclinical and clinical trials towards potential approval and commercialization, various aspects of the development program, such as manufacturing methods and formulation, may be altered along the way to optimize processes and results or due to other factors. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our current or future product candidates to perform differently and affect the costs, results, or timing of planned preclinical or clinical trials conducted with the altered materials. Such changes may also require additional testing, FDA notification or FDA approval. This could delay completion of preclinical studies or 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 product candidates, or jeopardize our ability to commence sales and generate revenue.

Due to our intention to rely in part on contract research organizations and other third parties to conduct clinical trials, we may be unable to directly control the timing, conduct, and expense of all aspects of our clinical trials.

We intend to rely in part on contract research organizations, electronic data capture companies, data management companies, contract clinical research associates, medical institutions, clinical investigators, contract laboratories, and other third parties to assist us in conducting clinical trials and obtaining regulatory approvals for our product candidates. In addition, we intend to rely in part on third parties to assist with our preclinical development of product candidates. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, need to be replaced, or the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our clinical protocols, regulatory requirements, or for other reasons, our preclinical development activities or clinical trials may be extended, delayed, suspended, or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates.

Risks Related to Our Intellectual Property

If we fail to comply with our obligations under any license, collaboration, or other agreement, including the Bayer License Agreement, we may be required to pay damages and could lose intellectual property rights that are necessary for developing and protecting our product candidates.

Pursuant to the Bayer License Agreement, we have been granted a license from Bayer to certain intellectual property rights covering enitociclib, VIP236, VIP943, VIP924, and our other product candidates. If, for any reason, our licenses under the Bayer License Agreement are terminated or we otherwise lose those rights, our business will be significantly and adversely affected. The Bayer License Agreement imposes, and any future collaboration agreements or license agreements we may choose to enter are likely to impose, various development, commercialization, funding, milestone payment, royalty, diligence, sublicensing, patent prosecution and enforcement, or other obligations on us. If we breach any material obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages, and Bayer and any other licensor may have the right to terminate the license, which could result in us being unable to develop, manufacture, and sell products that are covered by the licensed technology, or having to negotiate new or reinstated licenses on less favorable terms, or enable a competitor to gain access to the licensed technology.

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

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

In addition, the Bayer License Agreement under which we license our core intellectual property and technology is complex, and certain provisions in the agreement may be susceptible to multiple interpretations. The resolution of any disagreement that may arise as a matter of contract interpretation 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 that agreement, either of which could have a material adverse effect on our business. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidate, which could have a material adverse effect on our business and prospects.

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 enitociclib, VIP236, VIP943, VIP924, and our other 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 U.S. 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 will have licensed patents that cover enitociclib under the Bayer License Agreement, we do not have issued patents covering our other product candidates, and we may need additional issued patents covering enitociclib. 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 USPTO, courts in the U.S., or the patent offices and courts in foreign countries, nor can we be certain that the claims in our issued patents or our licensor's issued patents will not be found invalid or unenforceable if challenged.

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

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- patent applications may not result in any patents being issued;
- patents may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable, or otherwise may not provide any competitive advantage;
- our competitors, many of whom have substantially greater resources than we 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;
- 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 U.S. for disease treatments that prove successful as a matter of public policy regarding worldwide health concerns; and
- countries other than the U.S. 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, contract research organizations, 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 and obtain 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 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 U.S. 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 and inter partes review, or other similar proceedings challenging our owned patent rights. An adverse determination in any such submission, proceeding, or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, 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 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.

The validity, scope, and enforceability of any patents that cover a biologic subject to approval by the FDA via a BLA, such as VIP943 and VIP924, can be challenged by third parties.

For biologics subject to approval by the FDA via a BLA, such as VIP943 and VIP924, the BPCIA provides a mechanism for one or more third parties to seek FDA approval to manufacture or sell biosimilar or interchangeable versions of brand name biological products. If a biosimilar applicant successfully challenges our asserted patent claims, it could result in the invalidation of, or render unenforceable, some or all our relevant patent claims or result in a finding of non-infringement. Such litigation or other proceedings to enforce or defend our intellectual property rights are complex in nature, may be very expensive and time-consuming, may divert our management's attention from our core business, and may result in unfavorable results that could limit our ability to prevent third parties from competing with VIP943 and VIP924 or any future biological product candidates.

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, 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 patents or the patents of our licensors are invalid or unenforceable in whole or in part. In patent litigation in the U.S., defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description, non-enablement, or obviousness-type double patenting. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution.

Third parties may also raise similar invalidity claims before the USPTO or patent offices abroad, even outside the context of litigation, and prior art could render our patents or our licensors' patents invalid. Such mechanisms include re-examination, post-grant review, inter partes review, 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 they no longer cover our technology or platform, or any product candidates that we may develop. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. 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 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. In addition, if the breadth or strength of protection provided by our patents and patent applications or the patent 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 and prospects. Moreover, the issuance of a patent does not necessarily 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.

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, 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.

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

During 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 and prospects.

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.

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.

The Leahy-Smith America Invents Act of 2011 includes several significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith America Invents 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 file any patent application related to our product candidates or invent any of the inventions claimed in the patents or patent applications.

The Leahy-Smith America Invents Act also includes several significant changes that affect the way patent applications are 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 post-grant review, inter partes review, 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 America Invents 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.

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.

Obtaining and enforcing patents in the pharmaceutical industry involve a high degree of technological and legal complexity. 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, increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents and weaken our ability to obtain new patents or to enforce our existing patents and the patents we might obtain or license in the future.

We may be subject to claims challenging the inventorship or ownership of our licensor's patents, 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 licensor's patents, 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 patents or in-licensed patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984. The Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. 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.

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

Geopolitical actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution, maintenance, or enforcement of our patent applications or issued patents or those of

any current or future licensors. For example, United States and foreign government actions related to Russia's invasion of Ukraine have limited and prevented the filing, prosecution, and maintenance of patent applications and issued patents in Russia, and actions by the Russian government allow Russian companies and individuals to exploit inventions owned by patentees from the United States without consent or compensation. These actions could adversely affect our business.

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 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 applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of our licensor's patents and applications and those that we own. 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 many 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, 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 and unregistered trademarks or trade names to brand and market ourselves and our products. Our trademarks or trade names may be challenged, infringed, circumvented, or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks like 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. Our efforts to enforce or protect our proprietary rights related to trademarks and trade names may be ineffective and could result in substantial costs and diversion of resources. If we are unable to enforce and protect our trademarks and tradenames and establish name recognition based on our trademarks and trade names, we may not be able to compete effectively, and our business could be adversely affected.

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

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. 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. 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, agents, or consultants have wrongfully used or disclosed alleged confidential information or trade secrets.

We have entered 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, contract research organizations, third-party manufacturers, consultants, advisors, potential partners, and other third parties. In addition, we may engage employees, agents, and consultants to assist us in the development of our product candidates who were previously employed at, or have previously provided or are currently providing services to, other pharmaceutical companies, including our competitors or potential competitors. We may become subject to claims or litigation where a third party asserts that we or our employees, agents, or consultants inadvertently or otherwise used or disclosed trade secrets or other information proprietary to such third parties. Defense of such matters, regardless of their merit, could involve substantial litigation expense and be a substantial diversion from our business, and we cannot predict whether we would prevail in any such actions. In addition, third 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. Moreover, intellectual property litigation, regardless of its outcome, may cause negative publicity, result in the disclosure of our confidential information as a result of discovery, and adversely impact our ability to market or otherwise commercialize 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 and prospects. Even if we are successful in defending against these claims, such litigation could result in substantial costs and be a distraction to our management team and other employees.

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.

We may need to license intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

A third party may hold intellectual property, including patent rights, that are important or necessary to the development or commercialization of our product candidates. in which case we would be required to obtain a license from these third parties on commercially reasonable terms. Such a license may not be available, or it may not be available on commercially reasonable terms. Our business would be harmed if we are not able to obtain such a license on commercially reasonable terms or at all or if a non-exclusive license is offered and our competitors gain access to the same technology. In addition, even if we are able to obtain such a license, we may not have control over, nor the ability to provide input with respect to, the prosecution, maintenance, or enforcement of the patents that we license, and our licensors may fail to take the steps that we believe are necessary or desirable in order to obtain, maintain, defend, and enforce the licensed patents.

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, inter partes review proceedings, and post-grant review proceedings before the USPTO and 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 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 or, if we were found to be infringing willfully, result in treble damages;
- 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;

- require us to develop non-infringing technology, which may not be possible on a cost-effective basis;
- 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;
- subject us to significant liability to third parties; or
- divert the time and attention of our technical personnel and management.

Although no third party has asserted a claim of patent infringement against us as of the date of this report, others may hold proprietary rights that could prevent our product candidates from being marketed. For example, we are aware of issued patents that claim a method of treatment based upon a general mode of action. These claims could be alleged to cover enitociclib in certain treatment indications. While we believe that these patents are difficult to enforce and that we would have valid defenses to these claims of patent infringement, we cannot be certain that we would prevail in any dispute, and we cannot be certain how an adverse determination would affect our business.

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 material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business.

We may in the future pursue invalidity proceedings with respect to third-party patents. The outcome following legal assertions of invalidity is unpredictable. Even if resolved in our favor, these legal proceedings could distract our technical and management personnel from their normal responsibilities and may cause us to incur significant expenses, which could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. In addition, we may not have sufficient financial or other resources to conduct such proceedings adequately. Some of these third parties may be able to sustain the costs of such proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent proceedings could compromise our ability to compete in the marketplace. 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. If we do not prevail in the patent proceedings, such third parties may assert a claim of patent infringement directed at our technology or product candidates, which could have a material adverse effect on our business 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 in the future require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license, or use these third-party proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, processes, or other third party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and 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 progress and 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

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.

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.

General Risk Factors

Our stock price has been volatile and our stock has been thinly traded, and you may not be able to sell shares of our common stock at or above the price you paid.

The trading price of our common stock has been volatile and is subject to wide fluctuations. Since completion of the Business Combination, our common stock has been relatively thinly traded. As a result of the low trading volume of our common stock, the trading of relatively small quantities of shares by our stockholders could disproportionately influence the market price of our common stock in either direction. The price for our shares could, for example, decline significantly in the event that a large number of shares of our common stock are sold on the market without commensurate demand, as compared to an issuer with a higher trading volume that could better absorb those sales without an adverse impact on its stock price.

There are numerous factors that can influence our stock price volatility and trading volume, some of which are beyond our control. These factors could include:

- our ability to develop or commercialize products;

- results of our clinical trials and nonclinical studies;
- our capital requirements and capital raising activities, such as issuances of securities or the incurrence of debt;
- our ability to enter into collaboration agreements;
- actual or anticipated fluctuations in our financial results or the financial results of companies perceived to be similar;
- changes in the market's expectations about our operating results;
- success of competitors;
- our operating results failing to meet the expectation of securities analysts or investors in a particular period;
- changes in financial estimates and recommendations by securities analysts concerning us or the oncology industry in general;
- operating and share price performance of other companies that investors deem comparable to us;
- changes in laws and regulations affecting our business;
- our ability to meet compliance requirements and obtain regulatory approvals;
- our ability to obtain and maintain proprietary protection for our current and future product candidates;
- commencement of, or involvement in, litigation involving us;
- the volume of shares of our common stock available for public sale;
- any major change in our board of directors or management;
- sales of shares of common stock by our directors, executive officers, or significant stockholders, or the perception that such sales could occur; and
- general economic and political conditions such as recessions, interest rates, inflation, fuel prices, international currency fluctuations and acts of war or terrorism.

In addition, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies, particularly those in the biotechnology industry. These fluctuations have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors, as well as general economic, political, regulatory, and market conditions, may negatively affect the market price of our common stock, regardless of our actual operating performance.

Volatility in our stock price could subject us to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

There could be potential conflicts of interest between us and certain of our stockholders, which includes some of our executive officers, due to their right to designate a majority of the members of our board of directors.

Pursuant to the Voting and Support Agreement, entered into among the Legacy Holders and certain other stockholders in connection with the Business Combination (the "Voting Agreement"), the Legacy Holders,

including Dr. Ahmed M. Hamdy, our Chief Executive Officer, and Dr. Raquel E. Izumi, our President and Chief Operations Officer, have the right to designate seven of the nine members to our board of directors, and the stockholders who are parties to the Voting Agreement, who beneficially own approximately 33.6% of our outstanding common stock as of March 28, 2023, have agreed to vote for such designees. As a result, the Legacy Holders have the ability to exercise significant influence over the election of our board of directors, which in turn may create issues if and to the extent our interests and those of these stockholders diverge. We have not established at this time any procedural mechanisms to address actual or perceived conflicts of interest of such directors and officers and expect that our board of directors, in the exercise of its fiduciary duties, will determine how to address any actual or perceived conflicts of interest on a case-by-case basis.

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

If we fail to meet the continued listing requirements and Nasdaq delists our common stock, we could face significant material adverse consequences, including:

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

Any of the foregoing could harm investor confidence and the market price of our common stock.

If securities or industry analysts do not publish research or reports about us, or publish negative reports, our stock price and trading volume could decline.

The trading market for our common stock will depend, in part, on the research and reports that securities or industry analysts publish about us. We do not have any control over these analysts. If our operating results fail to meet analyst estimates or one or more of the analysts who cover us downgrade our common stock or change their opinion, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our stock price or trading volume to decline.

Future sales of shares of our common stock may depress the market price of our common stock.

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. As of March 28, 2023, private warrants to purchase 3,295,000 shares of common stock were outstanding. Additionally, up to 6,000,000 Earnout Shares may be issued in connection with the Merger Agreement, provided that certain conditions are met. To the extent such private warrants are exercised or conditions to receive Earnout Shares are met, additional shares of our common stock will be issued, which will result in dilution to the holders of our common stock and increase the number of shares eligible for resale in the public market. Such shares are eligible for sale in the public market, subject to volume limitations under Rule 144 under the Securities Act with respect to shares held by directors, executive officers, and other affiliates, and certain of such shares are eligible for sale in the public market under our currently effective Registration Statement on Form S-3. In addition, in September 2021, we sold 3,500,000 shares of our common stock to certain investors in a private placement, and such shares are available for resale under our Registration Statement on Form S-3. Sales, or potential sales, of substantial numbers of shares in the public market could increase the volatility of the market price of our common stock or adversely affect the market price of our common stock.

As a public company, we face increased expenses and administrative burdens, which could have an adverse effect on our business, financial condition, and results of operations.

As a public company, we face increased legal, accounting, administrative, and other costs and expenses. The Sarbanes-Oxley Act, including the requirements of Section 404, as well as rules and regulations subsequently implemented by the SEC, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 and the rules and regulations promulgated and to be promulgated thereunder, the Public Company Accounting Oversight Board, and the securities exchanges, impose additional reporting and other obligations on public companies. Compliance with public company requirements results in increased costs and makes certain activities more time-consuming, including expenses associated with SEC reporting requirements. In addition, if any issues in complying with those requirements are identified (for example, if the auditors identify a material weakness or significant deficiency in our internal control over financial reporting), we could incur additional costs in rectifying those issues, and the existence of those issues could adversely affect our reputation or investor perceptions of it. It is also more expensive to obtain director and officer liability insurance. Risks associated with our status as a public company may make it more difficult to attract and retain qualified persons to serve on our board of directors or as executive officers. The additional reporting and other obligations imposed by these rules and regulations increase our legal and financial compliance costs and the costs of related legal, accounting and administrative activities. These increased costs require us to divert a significant amount of money that could otherwise be used to expand our business and achieve our strategic objectives. Advocacy efforts by stockholders and third parties may also prompt additional changes in governance and reporting requirements, which could further increase costs.

We are an "emerging growth company" within the meaning of the Securities Act, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our stock less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including exemption from compliance with the auditor attestation requirements of Section 404, reduced disclosure obligations regarding executive compensation, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation, and stockholder approval of any golden parachute payments not previously approved. We will cease to be an emerging growth company on the date that is the earliest of (a) the last day of the fiscal year in which we have total annual gross revenue of $1.235 billion or more, (b) December 31, 2025, the last day of our fiscal year following the fifth anniversary of the date of the completion of our initial public offering, (c) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years, or (d) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

In addition, under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements including exemption from compliance with the auditor attestation requirements of Section 404 and reduced disclosure obligations regarding executive compensation in this report and our periodic reports and proxy statements.

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

Our Certificate of Incorporation provides, subject to limited exceptions, that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for certain stockholder litigation matters, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees, or stockholders.

Our Certificate of Incorporation requires, to the fullest extent permitted by law, that derivative actions brought in our name, actions against directors, officers, and employees for breach of fiduciary duty, and other similar actions may be brought solely and exclusively in the Court of Chancery in the State of Delaware or, if that court lacks subject matter jurisdiction, another federal or state court situated in the State of Delaware. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and consented to the forum provisions in our Certificate of Incorporation. In addition, our Certificate of Incorporation and Bylaws provide that the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action under the Securities Act and the Exchange Act. In March 2020, the Delaware Supreme Court issued a decision in Salzburg et al. v. Sciabacucchi, which found that an exclusive forum provision providing for claims under the Securities Act to be brought in federal court is facially valid under Delaware law. We intend to enforce this provision, but we do not know whether courts in other jurisdictions will agree with this decision or enforce it.

This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees, or stockholders, which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find the choice of forum provision contained in our Certificate of Incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business.

Concentration of ownership among our existing executive officers, directors, and their affiliates may prevent stockholders from influencing significant corporate decisions.

As of March 28, 2023, Dr. Ahmed M. Hamdy, our Chief Executive Officer, and Dr. Raquel E. Izumi, our President and Chief Operations Officer, beneficially owned, directly or indirectly, approximately 16.7% of our outstanding common stock, and our directors and executive officers as a group beneficially owned approximately 21.3% of our outstanding common stock. As a result, these stockholders will be able to exercise significant influence on all matters requiring stockholder approval, including the election of directors, any amendment of our Certificate of Incorporation and approval of significant corporate transactions. In addition, certain of these individuals are party to the Voting Agreement, pursuant to which the parties to the Voting Agreement have the right to nominate all of the members of our board of directors and the obligation to vote for such nominees. This could have the effect of delaying or preventing a change of control or changes in management and will make the approval of certain transactions difficult without the support of these stockholders.

Our failure to timely and effectively implement controls and procedures required by Section 404(a) of the Sarbanes-Oxley Act could have a material adverse effect on our business.

As a public company, we will be required to provide management's attestation on internal controls in the future under Section 404(a) of the Sarbanes-Oxley Act. Management may not be able to effectively and timely implement controls and procedures that adequately respond to these increased regulatory compliance and reporting requirements. If we are not able to implement the additional requirements of Section 404(a) in a timely manner or with adequate compliance, we may not be able to assess whether our internal controls over financial reporting are effective, which may subject us to adverse regulatory consequences and could harm investor confidence and the market price of our common stock.

Our management has limited experience in operating a public company.

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

We have never paid dividends on our capital stock and we do not anticipate paying dividends in the foreseeable future.

We have never paid dividends on any of our capital stock and currently intend to retain any future earnings to fund the growth of our business. In addition, we may enter into credit agreements or other borrowing arrangements in the future that will restrict our ability to declare or pay cash dividends on our common stock. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for the foreseeable future.

Any material weaknesses in or other inability to maintain effective internal control over financial reporting could adversely affect our ability to report our results of operations and financial condition accurately and in a timely manner.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with GAAP. Our management is likewise required, on a quarterly basis, to evaluate the effectiveness of our internal controls and to disclose any changes and material weaknesses identified through such evaluation in those internal controls. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

We identified a material weakness in our internal control over financial reporting related to the accounting and reporting for certain of our private warrants. Although management has concluded that this material weakness was remediated as of September 30, 2021, any future material weaknesses or other inability to maintain effective internal control over financial reporting could adversely impact our ability to report our financial position and results of operations on a timely and accurate basis. If our consolidated financial statements are not accurate, investors may not have a complete understanding of our operations and may lose confidence in our financial reporting and our business, reputation, results of operations, liquidity, financial condition, stock price and ability to access the capital markets could be adversely affected. In addition, we may be unable to maintain or regain compliance with applicable securities laws, stock market listing requirements and covenants regarding the timely filing of periodic reports, we may be subject to regulatory investigations and penalties, and we may face claims invoking the federal and state securities laws. Any such litigation or dispute, whether successful or not, could have a material adverse effect on our business.

ITEM 1B. Unresolved Staff Comments.

None.

ITEM 2. Properties.

Our principal executive offices are located in Palo Alto, California, and our lease agreement for such space expires in December 2025. Vincerx Pharma GmbH, our wholly owned German subsidiary, leases space in Monheim am Rhein, Germany. We do not own any real property. We believe that our office space is adequate to meet our current needs and that additional facilities will be available on commercially reasonable terms to meet our future needs.

ITEM 3. Legal Proceedings.

We are not currently a party to any legal proceedings, and are not aware of any pending or threatened legal proceedings against us that we believe could have a material adverse effect on our business, operating results or financial condition. We may from time to time become involved in legal proceedings arising in the ordinary course of business.

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.

Our common stock is listed on the Nasdaq Capital Market under the symbol "VINC."

As of March 28, 2023, there were 16 holders of record of our common stock and two holders of record of our private warrants. These numbers exclude holders whose stock or warrants are held in "street name" by brokers.

We have not paid any cash dividends on the common stock to date. We may retain future earnings, if any, for future operations, expansion and debt repayment and has no current plans to pay cash dividends for the foreseeable future. Any decision to declare and pay dividends in the future will be made at the discretion of our board of directors and will depend on, among other things, our results of operations, financial condition, cash requirements, contractual restrictions and other factors that our board of directors may deem relevant. In addition, our ability to pay dividends may be limited by covenants of any future outstanding indebtedness we or our subsidiaries may incur. We do not anticipate declaring any cash dividends to holders of the common stock in the foreseeable future.

ITEM 6. [Reserved].

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

The following discussion and analysis should be read in conjunction with our audited consolidated financial statements and related notes appearing elsewhere in this report. This discussion may contain forward-looking statements based on current expectations that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth in the section titled "Risk Factors" as set forth in this report. Historical results are not necessarily indicative of future results. Unless the context otherwise requires, references in this "Management's Discussion and Analysis of Financial Condition and Results of Operations" to "Vincerx", the "Company", "we", "us" and "our" refer to the business and operations of Vincerx prior to and following the closing of the Business Combination.

Overview

We are a clinical-stage biopharmaceutical company focused on leveraging our extensive development and oncology expertise to advance new therapies intended to address unmet medical needs for the treatment of cancer. Our current pipeline is entirely derived from the Bayer License Agreement, pursuant to which we have been granted an exclusive, royalty-bearing, worldwide license under certain Bayer patents and know-how to develop, use, manufacture, commercialize, sublicense and distribute (i) a clinical-stage and follow-on small molecule drug program, and (ii) a preclinical stage bioconjugation platform, which includes next-generation antibody-drug conjugates and small molecule drug conjugates.

Our small molecule drug program consists of enitociclib, currently in Phase 1, and our bioconjugation platform consists of a small molecule drug-conjugate for solid tumors, VIP236, in Phase 1, and preclinical next-generation antibody drug-conjugates, VIP943 and VIP924. We intend to use these product candidates to treat various cancers in a patient-specific, targeted approach. We believe that these product candidates are differentiated from current programs targeting similar cancer biology and, if approved, may improve clinical outcomes of patients with cancer.

License Agreement with Bayer

Following the closing of the Business Combination, we paid Bayer a $5.0 million upfront license fee under the Bayer License Agreement. In addition, we will be responsible for significant development and commercial milestone payments to Bayer as well as ongoing royalties on commercial sales. See "Business—Bayer License Agreement" and the discussion below under "Liquidity and Capital Resources."

Basis of Presentation

We currently conduct our business through one operating segment. As a pre-revenue company with no commercial operations, our activities to date have been limited and were conducted primarily in the United States. Our historical results are reported under GAAP and in U.S. dollars.

Components of Results of Operations

We are a research and development stage company, and our historical results may not be indicative of our future results for reasons that may be difficult to anticipate. Accordingly, the drivers of our future financial results, as well as the components of such results, may not be comparable to our historical results of operations.

Revenue

To date, we have not recognized any revenue from any sources, including from product sales, and we do not expect to generate any revenue from the sale of products in the foreseeable future. If our development efforts for our product candidates are successful and result in regulatory approval or license agreements with third parties, we may generate revenue in the future from product sales. However, there can be no assurance as to when we will generate such revenue, if at all.

Research and Development Expense

Research and development expenses consist or will consist of preclinical development of our product candidates and discovery efforts (including conducting preclinical studies), manufacturing development efforts, preparing for and conducting clinical trials, and activities related to regulatory filings for our product candidates. Research and development expenses are recognized as incurred and payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received. Costs incurred in obtaining technology licenses through asset acquisitions are charged to research and development expense if the licensed technology has not reached technological feasibility and has no alternative future use. Research and development expenses include or could include:

- employee-related expenses, including salaries, bonuses, benefits, stock-based compensation, and other related costs for those employees involved in research and development efforts;
- external research and development expenses incurred under agreements with clinical research organizations, investigative sites, and consultants to conduct our preclinical studies;
- costs related to manufacturing material for preclinical studies and clinical trials, including fees paid to contract manufacturing organizations;
- laboratory supplies and research materials;
- costs related to compliance with regulatory requirements; and
- facilities, depreciation, and other allocated expenses, which include direct and allocated expenses for rent, maintenance of facilities, insurance, and equipment.

Research and development activities are central to our business model. We do not currently intend to track our research and development expenses on a program-by-program basis as such costs will be deployed across

multiple projects under development. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We plan to increase our research and development expenses for the foreseeable future as we develop our product candidates and manufacturing processes and conduct discovery and research activities for our preclinical and clinical programs. We cannot determine with certainty the timing of initiation, the duration, or the completion costs of current or future preclinical studies and clinical trials of our product candidates due to the inherently unpredictable nature of preclinical and clinical development. Clinical and preclinical development timelines, the probability of success, and development costs can differ materially from expectations. We anticipate that we will make determinations as to which product candidates to pursue and how much funding to direct to each product candidate on an ongoing basis in response to the results of ongoing and future preclinical studies and clinical trials, regulatory developments, our ongoing assessments as to each product candidate's commercial potential, and our capital resources. Our clinical development costs are expected to increase significantly as we commence, continue, and expand our clinical trials. Our future expenses may vary significantly each period based on factors such as:

- expenses incurred to conduct preclinical development and studies required to advance our product candidates into clinical trials;
- per patient clinical trial costs, including based on the number of doses that patients receive;
- the number of patients who enroll in each clinical trial;
- the number of clinical trials required for approval;
- the number of sites included in the clinical trials;
- the countries in which the clinical trials are conducted;
- the length of time required to enroll eligible patients;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the clinical trials and follow-up;
- the phase of development of the product candidate;
- third party contractors failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- the cost of insurance, including product liability insurance, in connection with clinical trials;
- regulators or institutional review boards requiring that we or our investigators suspend or terminate clinical development for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks; and
- the efficacy and safety profile of our product candidates.

General and Administrative Expenses

General and administrative expenses consist or will consist principally of salaries and related costs for personnel in executive and administrative functions, including stock-based compensation, travel expenses and recruiting expenses. Other general and administrative expenses include professional fees for legal, accounting and tax-related services and insurance costs.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our expanded operations and infrastructure, as well as the initiation, continuation and expansion of our preclinical development and studies and clinical trials for our product candidates. We also

anticipate that our general and administrative expenses will increase as a result of payments for accounting, audit, legal and consulting services, as well as costs associated with maintaining compliance with Nasdaq listing rules and SEC requirements, director and officer liability insurance, investor and public relations activities and other expenses associated with operating as a public company.

Change in Fair Value of Warrant Liabilities

Certain of our private warrants are classified as liabilities pursuant to ASC 815-40, Derivatives and Hedging—Contracts in Entity's Own Equity. The change in fair value of warrant liabilities consists of the change in fair value of these private warrants.

Results of Operations

Comparison of the Years Ended December 31, 2022 and 2021

The following table sets forth our historical operating results for the periods indicated (amounts in thousands):

	For the years ended December 31,		
	2022	2021	Amount Change
Operating expenses:			
General and administrative	$ 18,953	$ 22,575	$ (3,622)
Research and development	52,152	40,081	12,071
Restructuring	2,469	—	2,469
Total operating expenses	73,574	62,656	10,918
Loss from operations	(73,574)	(62,656)	(10,918)
Other income (expense)			
Change in fair value of warrant liabilities	6,303	23,358	(17,055)
Interest income	664	—	664
Other income (expense)	1,240	(8)	1,248
Total other income (expense)	8,207	23,350	(15,143)
Net loss	**$(65,367)**	**$(39,306)**	**$(26,061)**

Research and Development

Research and development expenses increased by $12.1 million for the year ended December 31, 2022 compared to the year ended December 31, 2021. This increase primarily relates to increases in manufacturing services of approximately $9.1 million, including the initiation of manufacturing associated with our ADC program, third party research and preclinical work of approximately $7.0 million, new employee salaries of approximately $1.9 million, and clinical services of approximately $1.1 million, partially offset by a decline in stock-based compensation of approximately $7.7 million.

General and Administrative

General and administrative expenses decreased by approximately $3.6 million for year ended December 31, 2022 compared to the year ended December 31, 2021 primarily as a result of a decline in stock-based compensation expense of $3.6 million.

Restructuring

On June 4, 2022, our board of directors approved a strategic plan to prioritize and focus our resources on certain of our enitociclib clinical studies and our next generation bioconjugation platform and streamline and realign its resources to support these prioritized studies. This plan included a reduction of full-time employees by 33% and other cost reduction measures. Affected employees were offered separation benefits, including severance and reimbursement of healthcare premium payments.

We have incurred approximately $2.5 million of severance and related expenses for the year ended December 31, 2022. This includes approximately $0.5 million of stock-based compensation expense related to the acceleration of stock options to certain affected employees. No further restructuring expenses are expected to be incurred in connection with the restructuring.

Change in Fair Value of Warrant Liabilities

The change in fair value of warrant liabilities for the year ended December 31, 2022 compared to the prior year was primarily due to the decrease in the closing price of our common stock from $10.19 per share as of December 31, 2021 to $1.02 per share as of December 31, 2022.

Interest Income

Interest income is primarily comprised of interest income and gains or losses realized on cash, cash equivalents and marketable securities. The increase in interest income to $0.7 million for the year ended December 31, 2022 is a result of rising interest rates within our portfolio of cash equivalents and short-term marketable securities.

Other Income (Expense)

Other income (expense) is primarily comprised of estimated grant income of approximately $1.4 million earned in connection with our research activities conducted at our German subsidiary, partially offset by foreign currency transaction gains and losses related to certain transactions with European third-party vendors.

Liquidity and Capital Resources

Net working capital decreased from the year ended December 31, 2021 to the year ended December 31, 2022 by $51.1 million (to $46.8 million from $97.9 million) primarily as a result of cash used in operations of $59.6 million in fiscal 2022. In September 2021, we completed a private placement of 3.5 million shares of common stock, at a price of $14.50 per share. We received net proceeds from this private placement of approximately $47.4 million, after deducting transaction costs of approximately $3.3 million. We also received net proceeds of approximately $40.7 million from the redemption of warrants in 2021.

To date, we have not generated any revenue from any source, including the commercial sale of approved drug products, and we do not expect to generate revenue in the foreseeable future. If we fail to complete the development of our product candidates in a timely manner or fail to obtain their regulatory approval, our ability to generate future revenue will be materially adversely affected. We do not know when, or if, we will generate any revenue from our product candidates, and we do not expect to generate revenue unless and until we obtain regulatory approval of, and commercialize, our product candidates.

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue preclinical development and studies of, initiate, continue and expand clinical trials of, and seek marketing approval for, our product candidates. In addition, if we obtain approval for any of our product candidates, we expect to incur significant commercialization expenses related to sales, marketing, manufacturing and distribution. Furthermore, we expect to incur additional costs associated with operating as a public company.

We will also be responsible for significant payments to Bayer under the Bayer License Agreement. We paid Bayer an upfront license fee of $5.0 million following the closing of the Business Combination and the receipt of the Initial Qualified Financing. In addition, we will also be responsible to Bayer for significant future contingent payments under the Bayer License Agreement upon the achievement of certain development and commercial sales milestones as well as ongoing royalties on net commercial sales. The size and timing of these milestone payments will vary greatly depending on factors such as the particular licensed product, whether it involves a P-TEFb licensed product or a bioconjugation licensed product (and which bioconjugation program), the number of distinct disease indications, the number of different countries with respect to which the milestone is achieved and the level of net commercial sales, and it is therefore difficult to estimate the total payments that could become payable to Bayer and when those payments would be due. If we achieve all of the milestones for each of the countries and disease indications, we would be obligated to pay development and commercial milestone payments that range from $110.0 million to up to $318.0 million per licensed product, and upon successful commercialization of at least five licensed products, we could be required to pay aggregate milestone payments in excess of $1.0 billion. We will be required to pay certain of these milestone payments prior to the time at which we are able to generate sufficient revenue, if any, from commercial sales of any of our product candidates. In addition to milestone payments, we are also required to pay Bayer under the Bayer License Agreement ongoing royalties in the single digit to low double-digit percentage range on net commercial sales of licensed products.

We therefore anticipate that we will need substantial additional funding in connection with our continuing operations. As of December 31, 2022, we had approximately $52.5 million in cash, cash equivalents and marketable securities. We intend to devote our capital resources to the preclinical and clinical development of our product candidates, our public company compliance costs, certain of the milestone payments under the Bayer License Agreement, and for working capital and other general corporate purposes. In June 2022, our board of directors approved a strategic plan to prioritize and focus our resources on certain of our enitociclib studies and our next generation bioconjugation platform and to streamline and realign resources, including a 33% workforce reduction, to support these prioritized studies and programs and extend our estimated cash runway. Based on our current business plans and assumptions, we believe that our existing capital resources will be sufficient to fund our operating expenses and capital requirements into late 2024. Our estimate as to how long we expect our existing capital to be able to fund our operating expenses and capital requirements is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could result in less cash available to us or cause us to consume capital significantly faster than we currently anticipate, and we may need or choose to seek additional funds sooner than planned.

Because of the numerous risks and uncertainties associated with research, development, and commercialization of pharmaceutical drug products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the extent to which we develop, in-license, or acquire other product candidates and technologies in our product candidate pipeline;
- the costs and timing of process development and manufacturing scale-up activities associated with our product candidates and other programs as we advance them through preclinical and clinical development;
- the number and development requirements of product candidates that we may pursue;

- the costs, timing, and outcome of regulatory review of our product candidates;
- the timing and amount of our milestone payments to Bayer under the Bayer License Agreement;
- the extent to which we are able to enter into collaboration or other agreements that provide us with additional capital resources;
- our headcount growth and associated costs to the extent we expand our research and development capabilities and establish and expand our commercial infrastructure and operations;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales, and distribution, for any of our product candidates for which we receive marketing approval;
- royalty payments to Bayer under the Bayer License Agreement;
- the costs and timing of preparing, filing, and prosecuting patent applications, maintaining and enforcing our intellectual property rights, and defending any intellectual property-related claims;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval; and
- the costs of operating as a public company.

Identifying potential product candidates and conducting preclinical development and studies and clinical trials is a time-consuming, expensive, and uncertain process that takes many years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of product candidates that we do not expect to be commercially available in the near term, if at all.

Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. 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, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our stockholders, and the terms of these equity securities or this debt may restrict our ability to operate. Any future debt financing and equity financing, if available, may involve covenants limiting and restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, entering into profit-sharing or other arrangements, or declaring dividends. If we raise additional funds through collaborations, strategic alliances, or marketing, distribution, or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs, or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise capital when needed or on acceptable terms, we could be forced to delay, reduce, or eliminate our research and development programs or future commercialization efforts.

Our business operations, and those of third parties with whom we conduct business, have been, and could continue to be, adversely affected by health pandemics and epidemics, including COVID-19, and by economic, business and political events, including inflation and the war in Ukraine. The extent to which these factors could continue to impact our business and operations will depend on future developments that are highly uncertain and cannot be predicted with confidence. Management continues to evaluate the impact of these factors on our current operations and future plans and intends to take appropriate measures to help alleviate their impact, but there can be no assurance that these efforts will be successful and that these factors will not continue to have a negative effect on our financial position and results of operations.

Contractual Obligations and Commitments

Leases

On December 23, 2020, we entered into a five-year term lease agreement which commenced on January 1, 2021. In April and May 2021, the lease was amended to include additional space. The annual rent payments are approximately $1.2 million.

In connection with our strategic plan and workforce reduction (see note 5 to the consolidated financial statements), we have consolidated our leased office space at our corporate headquarters location. Effective July 2022, we have subleased substantially all of our remaining unused office space for a term of 18 months at a base rent of $50,000 per month. Such payments received in the year ended December 31, 2022 were $0.3 million.

Cash Flows

The following table provides a summary of our cash flow data for the periods indicated (amounts in thousands):

	For the years ended December 31,	
	2022	2021
Net cash used in operating activities	$(59,604)	$(33,402)
Net cash used in investing activities	$(40,578)	$ (5,258)
Net cash provided by financing activities	$ 280	$ 88,453

Cash Flows from Operating Activities

Our cash flows used in operating activities to date have been primarily comprised of payroll and professional service fees related to manufacturing, preclinical development and studies, clinical trials, and general and administrative activities. As we continue and expand clinical trials of, and seek marketing approval for, our product candidates, we expect our cash used in operating activities to increase before we start to generate any material cash flows from our business.

Net cash used in operating activities was approximately $59.6 million for the year ended December 31, 2022 compared to $33.4 million for the year ended December 31, 2021. Significant components of our cash used in operating activities consist primarily of payments to clinical and manufacturing service providers, payroll costs, and third-party professional services as we engage in preclinical development and studies and prepare for and conduct our clinical trials. Our net loss during the year ended December 31, 2022 was approximately $65.4 million, which included approximately $12.4 million related to stock-based compensation, offset by approximately $6.3 million income related to the change in fair value of warrant liabilities.

Cash Flows from Investing Activities

Cash used in investing activities was approximately $40.6 million for the year ended December 31, 2022, which consisted of purchases of marketable securities of $43.0 million, offset by $2.4 million of sales and maturities of marketable securities. Cash used in investing activities was approximately $5.3 million for the year ended December 31, 2021, which consisted of the payment to Bayer for the license fee and approximately $0.3 million for the purchase of furniture and fixtures for our facilities.

Cash Flows from Financing Activities

Net cash provided by financing activities was $0.3 million for the year ended December 31, 2022 compared to $88.5 million for the year ended December 31, 2021. The net cash provided by financing activities for the year ended December 31, 2022 consisted of proceeds received from the issuance of common stock under our employee stock plans. Net cash provided by financing activities for the year ended December 31, 2021 consisted

of $47.4 million in net proceeds received from the issuance of common stock in a private placement and $40.7 million in proceeds received from the exercise of our public warrants and certain of our private warrants.

Off-Balance Sheet Arrangements

We are not a party to any off-balance sheet arrangements, as defined under SEC rules.

Critical Accounting Policies and Estimates

Our consolidated financial statements have been prepared in accordance with GAAP. In the preparation of these consolidated financial statements, the management is required to use judgment in making estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities as of the date of the consolidated financial statements, as well as the reported expenses incurred during the reporting periods.

We consider an accounting judgment, estimate, or assumption to be critical when (1) the estimate or assumption is complex in nature or requires a high degree of judgment, and (2) the use of different judgments, estimates, and assumptions could have a material impact on the consolidated financial statements. Our significant accounting policies are described in Note 2 to our audited consolidated financial statements included elsewhere in this report. We have the critical accounting policies and estimates which are described below.

Research and Development

Research and development expenses may consist primarily of salaries, benefits, and other related costs and expenses, including stock-based compensation, in connection with preclinical development of our product candidates and discovery efforts (including conducting preclinical studies), manufacturing development efforts, preparing for and conducting clinical trials, and activities related to regulatory filings for our product candidates. In addition, research and development expenses may include payments to Bayer and other third parties for the development of our product candidates and the estimated fair value for the issuance of equity for the license rights to products in development (prior to marketing approval). Expenses related to clinical trials may be primarily related to activities at contract research organizations that design, gain approval for, and conduct clinical trials on our behalf. Such amounts are then recognized as an expense as the related goods are delivered or the services are performed.

Contingent Milestone Payments

As described above, we will be responsible for significant payments to Bayer under the Bayer License Agreement. We will be responsible to Bayer for significant future contingent payments under the Bayer License Agreement upon the achievement of certain development, regulatory, and commercial sales milestones. The size and timing of these milestone payments will vary greatly depending on numerous factors outlined above.

The transactions provided for under the Bayer License Agreement will be accounted for as an asset acquisition. Contingent consideration in an asset acquisition is generally recognized when it is probable that a liability has been incurred, and the amount can be reasonably estimated. In connection with the successful filing of our IND for VIP236 in December 2022, we have become obligated to pay a $1.0 million development milestone to Bayer under the Bayer License Agreement. No further milestone payments are probable, and no further liabilities had been incurred as of the date of this filing.

Income Taxes

Income taxes are recorded in accordance with ASC 740, Income Taxes, or ASC 740, which provides for deferred taxes using an asset and liability approach. We recognize deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the consolidated financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial

statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse, and net operating loss carryforwards and research and development tax credit carryforwards. Valuation allowances are provided if based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. We have recorded a full valuation allowance to reduce our net deferred income tax assets to zero. In the event we were to determine that we would be able to realize some or all of our deferred income tax assets in the future, an adjustment to the deferred income tax asset valuation allowance would increase income in the period such determination was made.

Stock-Based Compensation

We recognize the cost of share-based awards granted to employees, non-employees, and directors based on the estimated grant-date fair value of the awards. Cost is recognized on a straight-line basis over the service period, which is generally the vesting period of the award. We reverse previously recognized costs for unvested options in the period that forfeitures occur. We determine the fair value of stock options using the Black-Scholes option pricing model, which is impacted by the following assumptions:

- *Expected Term*—We use the simplified method when calculating the expected term due to insufficient historical exercise data.
- *Expected Volatility*—Given the limited market trading history of our common stock, volatility is based on a benchmark of comparable companies within the biopharmaceutical industry.
- *Expected Dividend Yield*—We have never paid any cash dividends on common stock and do not anticipate doing so in the foreseeable future.
- *Risk-Free Interest Rate*—The interest rates used are based on the implied yield available on U.S. Treasury zero-coupon issues with an equivalent remaining term equal to the expected life of the award.

Private Common Stock Warrant Liabilities

As of December 31, 2022, there were 3,295,000 private warrants to purchase common stock outstanding.

Each unit consisted of one share of common stock and one public warrant exercisable for one-half of one share of common stock. Each public warrant entitled the registered holder to purchase one-half (1/2) of a share of common stock at a price of $11.50 per whole share of common stock, subject to adjustment as discussed below, at any time commencing on the later of one year after the closing of the initial public offering of LSAC or the consummation of a business combination.

The private warrants are identical to the warrants underlying the units except that (i) each private warrant is exercisable for one share of common stock at an exercise price of $11.50 per share and (ii) such private warrants will be exercisable for cash (even if a registration statement covering the shares of common stock issuable upon exercise of such private warrants is not effective) or on a cashless basis, at the holder's option (except with respect to 500,000 of the private warrants held by Rosedale Park, LLC and 500,000 of the private warrants held by LifeSci Holdings LLC, which were amended to remove the cashless exercise provision), and will not be redeemable by us (except with respect to 500,000 of the private warrants held by Rosedale Park, LLC and 500,000 of the private warrants held by LifeSci Holdings LLC, which were amended to include a redemption provision substantially identical to that of the public warrants; provided, however, that such redemption rights may not be exercised during the first 12 months following the closing of the Business Combination unless the last sales price of our common stock has been equal to or greater than $20.00 per share for any 20 trading days within a 30 trading day period ending on the third business day prior to the date on which notice of redemption is given), in each case so long as they are still held by the initial purchasers or their affiliates. The private warrants purchased by Rosedale Park, LLC, will expire on March 5, 2025, provided that once the private warrants are not beneficially owned by Chardan Capital Markets, LLC or any of its related persons anymore, the private warrants may not be exercised five years following the completion of our business combination.

We evaluated the public and private warrants under ASC 815-40, Derivatives and Hedging—Contracts in Entity's Own Equity, and concluded that certain of the private warrants do not meet the criteria to be classified in stockholders' equity. Because post Business Combination, these private warrants could be transferred to a non-permitted transferee and become public warrants (i.e., become subject to redemption and no longer have a cashless exercise feature), the settlement value of the private warrants is dependent, in part, on the holder of these private warrants at the time of settlement. Because the holder of an instrument is not an input into the pricing of a fixed-for-fixed option on our common stock, these private warrants fail the indexation guidance in ASC 815-40. This conclusion excludes the 500,000 private warrants held by LifeSci Holdings LLC, which had been amended in connection with the Business Combination to remove the cashless exercise provision and include a redemption provision, as described above.

Since these private warrants meet the definition of a derivative under ASC 815, we recorded these warrants as liabilities on the balance sheet at fair value, with subsequent changes in their respective fair values recognized in the consolidated statement of operations and comprehensive loss at each reporting date. The estimated fair value of the private warrants is determined with Level 3 inputs using Black-Scholes and Monte Carlo simulations. The private warrants were valued as of December 31, 2022 and December 31, 2021. See Note 6.

Emerging Growth Company Status

Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can choose not to take advantage of the extended transition period and comply with the requirements that apply to non-emerging growth companies, and any such election to not take advantage of the extended transition period is irrevocable.

We are an "emerging growth company" as defined in Section 2(a) of the Securities Act and have elected to take advantage of the benefits of the extended transition period for new or revised financial accounting standards. We expect to remain an emerging growth company through the end of the 2025 fiscal year and expect to continue to take advantage of the benefits of the extended transition period, although we may decide to early adopt such new or revised accounting standards to the extent permitted by such standards. This may make it difficult or impossible to compare our financial results with the financial results of another public company that is either not an emerging growth company or is an emerging growth company that has chosen not to take advantage of the extended transition period exemptions because of the potential differences in accounting standards used.

Recent Accounting Pronouncements

See Note 2 to the audited consolidated financial statements in this report for more information about recent accounting pronouncements, the timing of their adoption, and our, to the extent it has made one, review of their potential impact on our financial condition and results of operations and cash flows.

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

We are exposed to market risks in the ordinary course of our business, including the effects of interest rate changes and fluctuations in foreign currency exchange rates. Information on quantitative and qualitive disclosures about these market risks is set forth below.

Interest Rate Risk

Cash and restricted cash consists solely of cash held in depository accounts and as such are not affected by either an increase or decrease in interest rates. Furthermore, we consider all highly liquid investments as cash equivalents. As of December 31, 2022, we possess cash equivalents and short-term marketable securities. The short-term nature of these investments are not significantly impacted by changes in the interest rates. Any

interest-bearing instruments carry a degree of risk; however, we have not been exposed to, nor do we anticipate being exposed to, material risks due to changes in interest rates. A hypothetical 10% change in interest rates during any of the periods presented would not have had a material impact on our consolidated financial statements.

Foreign Currency Risk

Our operations are principally denominated by U.S. dollars and we do not expect our future operating results to be significantly affected by foreign currency transaction risk. A hypothetical 10% change in foreign exchange rates during any of the periods presented would not have had a material impact on our consolidated financial statements.

ITEM 8. Financial Statements and Supplementary Data.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of Vincerx Pharma, Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Vincerx Pharma, Inc. (the "Company") as of December 31, 2022 and 2021, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2022, 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 as of December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

/s/ WithumSmith+Brown, PC

We have served as the Company's auditor since 2020

Whippany, New Jersey

March 28, 2023

PCAOB ID Number 100

Vincerx Pharma, Inc.
Consolidated Balance Sheets

(In thousands, except share and per share amounts)

	December 31, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 11,663	$111,459
Restricted cash	70	105
Short-term marketable securities	40,796	—
Prepaid expenses	134	182
Other current assets	3,301	95
Total current assets	55,964	111,841
Right-of-use assets, net	3,064	3,949
Property, plant and equipment, net	177	233
Other assets	81	1,653
Total assets	**$ 59,286**	**$117,676**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 3,065	$ 2,019
Accrued expenses	4,923	4,715
Lease liability	1,024	738
Common stock warrant liabilities	144	6,447
Total current liabilities	9,156	13,919
Lease liability, net of current portion	2,412	3,436
Other noncurrent liabilities	50	—
Total liabilities	11,618	17,355
Commitments and contingencies—Note 9		
Stockholders' equity		
Preferred stock, $0.0001 par value; 30,000,000 shares authorized, none issued and outstanding as of December 30, 2022 and 2021	—	—
Common stock, $0.0001 par value; 120,000,000 shares authorized; 21,242,884 shares and 21,057,560 shares issued and outstanding as of December 31, 2022 and 2021, respectively	2	2
Additional paid-in capital	169,030	156,311
Accumulated other comprehensive loss	(26)	(21)
Accumulated deficit	(121,338)	(55,971)
Total stockholders' equity	47,668	100,321
Total liabilities and stockholders' equity	**$ 59,286**	**$117,676**

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

Vincerx Pharma, Inc.
Consolidated Statements of Operations and Comprehensive Loss

(In thousands, except per share amounts)

	For the years ended December 31,	
	2022	**2021**
Operating expenses:		
General and administrative	$ 18,953	$ 22,575
Research and development	52,152	40,081
Restructuring	2,469	—
Total operating expenses	73,574	62,656
Loss from operations	(73,574)	(62,656)
Other income (expense)		
Change in fair value of warrant liabilities	6,303	23,358
Interest income	664	—
Other income (expense), net	1,240	(8)
Total other income (expense)	8,207	23,350
Net loss	**$(65,367)**	**$(39,306)**
Other comprehensive loss:		
Net foreign currency translation gain (loss)	69	(21)
Net unrealized loss on marketable securities	(74)	—
Comprehensive loss	**$(65,372)**	**$(39,327)**
Net loss per common share, basic and diluted	$ (3.11)	$ (2.29)
Weighted average common shares outstanding, basic and diluted	21,029	17,176

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

Vincerx Pharma, Inc.
Consolidated Statements of Changes in Stockholders' Equity

(In thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of January 1, 2021	**13,984**	**$ 1**	**$ 42,043**	**$ —**	**$ (16,665)**	**$ 25,379**
Issuance of common stock from private placement, net of transaction costs of $3,320	3,500	1	47,430	—	—	47,431
Issuance of common stock from warrant exercises	3,537	—	40,671	—	—	40,671
Issuance of common stock from employee stock plans	36	—	351	—	—	351
Reclassification of warrant liabilities to equity due to warrant exercises for cash	—	—	2,503	—	—	2,503
Stock-based compensation	—	—	23,313	—	—	23,313
Cumulative translation adjustment	—	—	—	(21)	—	(21)
Net loss	—	—	—	—	(39,306)	(39,306)
Balance as of December 31, 2021	**21,057**	**2**	**156,311**	**(21)**	**(55,971)**	**100,321**
Issuance of common stock from employee stock plans	186	—	280	—	—	280
Stock-based compensation	—	—	12,439	—	—	12,439
Cumulative translation adjustment	—	—	—	69	—	69
Unrealized loss on marketable securities	—	—	—	(74)	—	(74)
Net loss	—	—	—	—	(65,367)	(65,367)
Balance as of December 31, 2022	**21,243**	**$ 2**	**$ 169,030**	**$ (26)**	**$(121,338)**	**$ 47,668**

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

Vincerx Pharma, Inc.
Consolidated Statements of Cash Flows

(In thousands)

	For the years ended December 31,	
	2022	**2021**
Cash flows from operating activities		
Net loss	$ (65,367)	$ (39,306)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	54	25
Stock-based compensation	12,439	23,313
Amortization of right-of-use assets	885	315
Change in fair value of warrant liabilities	(6,303)	(23,358)
Net amortization of discounts on marketable securities	(292)	—
Changes in operating assets and liabilities:		
Prepaid and other current assets	(3,158)	1,041
Other assets	1,572	(1,571)
Accounts payable	1,046	1,528
Accrued expenses	208	4,715
Lease liability	(738)	(90)
Other noncurrent liabilities	50	—
Due to related parties	—	(14)
Net cash used in operating activities	(59,604)	(33,402)
Cash Flows from Investing Activities:		
Purchases of marketable securities	(42,978)	—
Sales and maturities of marketable securities	2,400	—
Research and development-acquired license	—	(5,000)
Capital expenditures	—	(258)
Net cash used in investing activities	(40,578)	(5,258)
Cash Flows from Financing Activities:		
Proceeds from issuance of common stock from employee stock plans	280	351
Proceeds from private placement, net of transaction costs	—	47,431
Proceeds from warrants exercised for cash, net of redemption cost	—	40,671
Net cash provided by financing activities	280	88,453
Effect of exchange rate changes on cash, cash equivalents and restricted cash	71	(21)
Net increase (decrease) in cash, cash equivalents and restricted cash	(99,831)	49,772
Cash, cash equivalents and restricted cash at beginning of year	111,564	61,792
Cash, cash equivalents and restricted cash at end of year	**$ 11,733**	**$ 111,564**
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ —	$ 25
Supplemental schedule of non-cash investing and financing activities:		
Reclassification of warrant liabilities to equity due to warrant exercises for cash	$ —	$ 2,503
Right-of-use assets obtained in exchange for operating lease liabilities	$ —	$ 4,264

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

Vincerx Pharma, Inc.
Notes to Consolidated Financial Statements

December 31, 2022 and 2021

1. Nature of Business

LSAC was initially formed on December 19, 2018 as a Delaware corporation for the purpose of effecting a merger, share exchange, asset acquisition, share purchase, reorganization, or similar business combination with one or more businesses. In December 2020, the Merger Sub merged with and into Legacy Vincera Pharma, with Legacy Vincera Pharma surviving the Merger as a wholly- owned subsidiary of LSAC. In connection with the Business Combination, LSAC changed its name to Vincera Pharma, Inc., and subsequently in January 2021, changed its name to Vincerx Pharma, Inc. (together with its consolidated subsidiaries, the "Company").

The Company is a clinical-stage biopharmaceutical company focused on leveraging its extensive development and oncology expertise to advance new therapies intended to address unmet medical needs for the treatment of cancer. The Company's current pipeline is entirely derived from the Bayer License Agreement (see Note 4), pursuant to which the Company has been granted an exclusive, royalty-bearing, worldwide license under certain Bayer patents and know-how to develop, use, manufacture, commercialize, sublicense, and distribute a clinical-stage and follow-on small molecule drug program and a preclinical stage bioconjugation platform, which includes next-generation antibody-drug conjugates and small molecule drug conjugates. The Company intends to use these product candidates to treat various cancers in a patient-specific, targeted approach.

The Company's business operations, and those of third parties with whom the Company conducts business, have been, and could continue to be, adversely affected by health pandemics and epidemics, including COVID-19, and by economic, business and political events, including inflation and the war in Ukraine. The extent to which these factors could continue to impact the Company's business and operations will depend on future developments that are highly uncertain and cannot be predicted with confidence. Management continues to evaluate the impact of these factors on the Company's current operations and future plans and intends to take appropriate measures to help alleviate their impact, but there can be no assurance that these efforts will be successful and that these factors will not continue to have a negative effect on the Company's financial position and results of its operations.

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company's consolidated financial statements have been prepared in conformity with GAAP as determined by the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") and pursuant to the regulations of the U.S. Securities and Exchange Commission ("SEC"). They include the accounts of Vincerx and its wholly-owned subsidiaries VNRX Corp. and Vincerx Pharma GmbH. All intercompany accounts and transactions have been eliminated.

Emerging Growth Company

The Company is an "emerging growth company," as defined in Section 2(a) of the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"), and it may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the independent registered public accounting firm attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in its periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

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

Use of Estimates

The preparation of financial statements in accordance with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of commitments and contingencies at the date of the financial statements as well as reported amounts of expenses during the reporting periods. Estimates made by the Company include, but are not limited to, common stock warrant liabilities and stock-based compensation. The Company bases these estimates on historical experience and on various other assumptions that it believes are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying amounts of assets and liabilities that are not readily apparent from other sources. Actual results could differ materially from those estimates.

Concentrations of Credit Risk

The Company has significant cash balances at financial institutions which throughout the year regularly exceed the federally insured limit of $250,000. Any loss incurred or a lack of access to such funds could have a significant adverse impact on the Company's financial condition, results of operations, and cash flows.

The Company is subject to risks common to companies in the biotechnology industry, including, but not limited to, development by the Company or its competitors of technological innovations, risks of failure of clinical studies, dependence on key personnel, protection of proprietary technology, compliance with government regulations, and ability to transition from preclinical manufacturing to commercial production of products.

The Company's future product candidates will require approvals from the U.S. Food and Drug Administration and comparable foreign regulatory agencies prior to commercial sales in their respective jurisdictions. There can be no assurance that any product candidates will receive the necessary approvals. If the Company was denied approval, approval was delayed or the Company was unable to maintain approval for any product candidate, it could have a material adverse impact on the Company.

Cash and Cash Equivalents

Management considers all highly liquid investments with an insignificant interest rate risk and original maturities of three months or less to be cash equivalents. There were no cash equivalents as of December 31, 2021.

Restricted Cash

Restricted cash represents cash deposits with a financial institution in support of letters of our corporate credit card program.

Marketable Securities

The Company generally invests its excess cash in money market funds and investment grade short-term to intermediate-term fixed income securities. Such investments are included in cash and cash equivalents, short-term marketable securities or long-term marketable securities on the consolidated balance sheets. Marketable securities with a maturity date greater than 90 days and less than one year at each consolidated balance sheet date are classified as short-term. Marketable securities with a maturity date greater than one year, if any, are classified as long-term. All of the Company's marketable securities are considered available-for-sale and are reported at fair value with unrealized gains and losses included as a component of stockholders' equity. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity, which is included in interest income on the consolidated statements of operations and comprehensive loss. Realized gains and losses and declines in value judged to be other-than-temporary, if any, on marketable securities are included in interest income on the consolidated statements of operations and comprehensive loss. The cost of securities sold is determined using specific identification.

The Company periodically evaluates whether declines in the fair values of its marketable securities below their amortized cost are other-than-temporary. This evaluation consists of several qualitative and quantitative factors regarding the severity and duration of the unrealized loss, as well as the Company's ability and intent to hold the marketable security until a forecasted recovery occurs. Additionally, the Company assesses whether it has plans to sell the marketable security or it is more likely than not it will be required to sell any marketable securities before recovery of its amortized cost basis. Factors considered include quoted market prices, recent financial results and operating trends, implied values from any recent transactions or offers of investee securities, credit quality of debt instrument issuers, other publicly available information that may affect the value of the marketable security, duration and severity of the decline in value, and the Company's strategy and intentions for holding the marketable security.

Property, Plant and Equipment

Property and equipment are stated at cost. Depreciation and amortization are provided for using straight-line methods, in amounts sufficient to charge the cost of depreciable assets to operations over their estimated service lives. Repairs and maintenance costs are charged to operations as incurred.

The Company assesses its long-lived assets for impairment whenever facts and circumstances indicate that the carrying amounts may not be fully recoverable. To analyze recoverability, the Company projects undiscounted net future cash flows over the remaining lives of such assets. If these projected undiscounted net future cash flows are less than the carrying amounts, an impairment loss would be recognized, resulting in a write-down of the assets with a corresponding charge to earnings. The impairment loss is measured based upon the difference between the carrying amounts and the fair values of the assets. There has been no impairment loss as of December 31, 2022.

Fair Value Measurement

The Company applies fair value accounting for all financial assets and liabilities measured on a recurring and nonrecurring basis. Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. 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 a liability. The accounting guidance established a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, used to determine the fair value of its financial instruments. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

Level 1—Quoted prices in active markets for identical assets or liabilities that the entity has the ability to access.

Level 2—Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets and liabilities.

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

Private Warrant Liability

As of December 31, 2022 and 2021, there were 3,295,000 private warrants to purchase common stock outstanding. As of December 31, 2020, there were 10,133,767 warrants outstanding, consisting of 6,563,767 public warrants (which included 2,744,586 public warrants constituting part of the units) and 3,570,000 private warrants. Each unit consisted of one share of common stock and one public warrant exercisable for one-half of one share of common stock.

Each public warrant entitled the registered holder to purchase one-half (1/2) of a share of common stock at a price of $11.50 per whole share of common stock, subject to adjustment as discussed below, at any time commencing on the later of one year after the closing of the initial public offering of LSAC or the consummation of a business combination.

The private warrants are identical to the warrants underlying the units except that (i) each private warrant is exercisable for one share of common stock at an exercise price of $11.50 per share and (ii) such private warrants will be exercisable for cash (even if a registration statement covering the shares of common stock issuable upon exercise of such private warrants is not effective) or on a cashless basis, at the holder's option (except with respect to 500,000 of the private warrants held by Rosedale Park, LLC and 500,000 of the private warrants held by LifeSci Holdings LLC, which were amended to remove the cashless exercise provision), and will not be redeemable by the Company (except with respect to 500,000 of the private warrants held by Rosedale Park, LLC and 500,000 of the private warrants held by LifeSci Holdings LLC, which were amended to include a redemption provision substantially identical to that of the public warrants; provided, however, that such redemption rights may not be exercised during the first 12 months following the closing of the Business Combination unless the last sales price of the Company's common stock has been equal to or greater than $20.00 per share for any 20 trading days within a 30 trading day period ending on the third business day prior to the date on which notice of redemption is given), in each case so long as they are still held by the initial purchasers or their affiliates. The private warrants purchased by Rosedale Park, LLC will expire on March 5, 2025, provided that once the private warrants are not beneficially owned by Chardan Capital Markets, LLC or any of its related persons anymore, the private warrants may not be exercised five years following the completion of the Business Combination.

The Company evaluated the public and private warrants under ASC 815-40, Derivatives and Hedging—Contracts in Entity's Own Equity, and concluded that certain of the private warrants do not meet the criteria to be classified in stockholders' equity. Because post Business Combination, these private warrants could be transferred to a non-permitted transferee and become public warrants (i.e., become subject to redemption and no longer have a cashless exercise feature), the settlement value of the private warrants is dependent, in part, on the holder of these private warrants at the time of settlement. Because the holder of an instrument is not an input into the pricing of a fixed-for-fixed option on the Company's common stock, these private warrants fail the indexation guidance in ASC 815-40. This conclusion excludes the 500,000 private warrants held by LifeSci Holdings LLC, which had been amended in connection with the Business Combination to remove the cashless exercise provision and include a redemption provision, as described above.

Since these private warrants meet the definition of a derivative under ASC 815, the Company recorded these warrants as liabilities on the consolidated balance sheet at fair value, with subsequent changes in their respective fair values recognized in the consolidated statements of operations at each reporting date. The estimated fair value of the private warrants is determined with Level 3 inputs using Black-Scholes and Monte Carlo simulations.

Leases

Effective January 1, 2021, the Company adopted FASB ASC Topic 842, "Leases" ("ASC 842"), using the required modified retrospective approach and utilizing the effective date as its date of initial application, for which prior periods are presented in accordance with the previous guidance in ASC 840, "Leases".

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present in the arrangement. Most leases with a term greater than one year are recognized on the balance sheet as right-of-use assets and short-term and long-term lease liabilities, as applicable. The Company has elected not to recognize on the balance sheet leases with terms of 12 months or less. The Company typically only includes an initial lease term in its assessment of a lease arrangement. Options to renew a lease are not included in the Company's assessment unless there is reasonable certainty that the Company will renew.

Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected remaining lease term. Certain adjustments to the right-of-use assets may be required for items such as incentives received. The interest rate implicit in the Company's leases is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate, which reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term and in a similar economic environment (see Note 9).

In accordance with ASC 842, components of a lease should be allocated between lease components (e.g., land, building, etc.) and non-lease components (e.g., common area maintenance, consumables, etc.). The fixed and in-substance fixed contract consideration (including any consideration related to non-components) must be allocated based on the respective relative fair values to the lease components and non-lease components.

Segments

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. The Company views its operations and manages its business as a single operating segment.

Research and Development Costs

The Company expenses research and development costs as operating expenses as incurred. These expenses include acquired in-process research and development expenses for which there is no alternative future use, salaries for research and development personnel, consulting fees, product development, pre-clinical studies, clinical trial costs, and other fees and costs related to the development of the technology.

Stock-Based Compensation

The Company measures and recognizes compensation expense for all stock-based awards made to employees, directors, and non-employees, including stock options and restricted shares, based on estimated fair values recognized over the requisite service period.

The fair value of options granted is estimated on the grant date using the Black-Scholes option valuation model. This valuation model for stock-based compensation expense requires the Company to make assumptions and judgments about the variables used in the calculation, including the expected term (weighted-average period of time that the options granted are expected to be outstanding), the volatility of the Company's common stock, and an assumed risk-free interest rate. The Company accounts for forfeitures when they occur. The Company uses the simplified calculation of the expected life, which takes into consideration the grant's contractual life and vesting period and assumes that all options will be exercised between the vesting date and the contractual term of the option. No awards have been issued with a market condition or other non-standard terms.

The estimate for volatility is based on an average of the historical volatilities of the common stock of several entities with characteristics similar to those of the Company. Since these comparable companies operate in the same industry segment, the Company expects that it would share similar characteristics, such as risk profiles, volatility, capital intensity and market growth patterns and drivers.

The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant for periods corresponding with the expected life of the option.

Income Taxes

Income taxes are recorded in accordance with ASC 740, "Income Taxes" ("ASC 740"), which provides for deferred taxes using an asset and liability approach. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse, and net operating loss carryforwards and research and development tax credit ("R&D Credit") carryforwards. Valuation allowances are provided, if based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. The Company has recorded a full valuation allowance to reduce its net deferred income tax assets to zero. In the event the Company were to determine that it would be able to realize some or all its deferred income tax assets in the future, an adjustment to the deferred income tax asset valuation allowance would increase income in the period such determination was made.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit would more likely than not be realized assuming examination by the taxing authority. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. At December 31, 2022 and 2021, the Company had no liability for income tax associated with uncertain tax positions. The Company would recognize any corresponding interest and penalties associated with its income tax positions in income tax expense. There was no income tax interest or penalties incurred in 2022 or 2021.

German Grant Income

The Company recognizes grant income in the period when the underlying eligible expenses are incurred. The German government grant program provides for tax refunds or direct reimbursements of eligible research expenses of up to 1.0 million euros per year over a period of six years. The grant was approved in 2022 and is retroactive to 2021. Grant income for the years ended December 31, 2022 and 2021 has been recorded in other income (expense), net on our consolidated statements of operations and comprehensive loss. The corresponding receivable is included within other current assets on our consolidated balance sheet and is expected to be collected within twelve months of the balance sheet date.

Foreign Currency Translation and Transactions

Our consolidated financial statements are presented in U.S. dollars. The functional currency for our foreign subsidiary is the local currency, or euro. Expenses, gains and losses for this entity are translated into U.S. dollars using average currency exchange rates for the period. Assets and liabilities are translated using exchange rates in effect at the balance sheet date. Foreign currency translation adjustments are recorded as a component of accumulated other comprehensive loss on our consolidated balance sheets. Foreign currency transaction gains and losses on transactions not denominated in the functional currency are recorded in other income (expense), net, on our consolidated statements of operations and comprehensive loss.

Comprehensive Income or Loss

Comprehensive loss is equal to net loss, net foreign currency translation loss, and net unrealized loss on marketable securities as presented in the accompanying consolidated statements of operations and comprehensive loss.

Net Loss per Share of Common Stock

Basic net loss per share is computed by dividing the net loss by the weighted-average number of shares of common stock outstanding during the period.

Diluted earnings per share adjusts basic earnings per share for the potentially dilutive impact of stock options and warrants. As the Company has reported losses for all periods presented, all potentially dilutive securities including stock options and warrants, are antidilutive and accordingly, basic net loss per share equals diluted net loss per share.

Recent Accounting Pronouncements

In August 2020, the FASB issued ASU 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, which simplifies accounting for convertible instruments by removing major separation models required under current GAAP. The ASU removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception and it also simplifies the diluted earnings per share calculation in certain areas. The ASU is effective for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2021 and adoption must be as of the beginning of the Company's annual fiscal year. The Company elected to early adopt this guidance on January1, 2022 without any material impact on its consolidated financial statements.

In May 2021, the FASB issued ASU 2021-04, "Earnings Per Share (Topic 260), Debt-Modifications and Extinguishments (Subtopic 470-50), Compensation-Stock Compensation (Topic 718), and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40)". This ASU reduces diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options (for example, warrants) that remain equity classified after modification or exchange. This ASU provides guidance for a modification or an exchange of a freestanding equity-classified written call option that is not within the scope of another Topic. It specifically addresses: (1) how an entity should treat a modification of the terms or conditions or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange; (2) how an entity should measure the effect of a modification or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange; and (3) how an entity should recognize the effect of a modification or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange. This ASU will be effective for all entities for fiscal years beginning after December 15, 2021. An entity should apply the amendments prospectively to modifications or exchanges occurring on or after the effective date of the amendments. Early adoption is permitted, including adoption in an interim period. The adoption of ASU 2021-04 on January 1, 2022 did not have a material impact on the Company's consolidated financial statements or disclosures.

3. Business Combination

As discussed in Note 1, on December 23, 2020, the Company consummated the Business Combination, with Legacy Vincera Pharma surviving the merger as a wholly-owned subsidiary of the Company.

Immediately prior to the effective time of the Business Combination, each share of Legacy Vincerx Pharma Common Stock was canceled, and the Legacy Holders received (i) 0.570895 shares of common stock, for each

share of Vincera Pharma common stock held by them immediately prior to the effective time of the Business Combination and (ii) certain rights to Earnout Shares after the closing of the Business Combination.

The Vincera Pharma stockholders are entitled to receive Earnout Shares if the daily volume-weighted average price of the Company's common stock equals or exceeds the following prices for any 20 trading days within any 30 trading-day period following the closing of the Business Combination: (1) during any such trading period prior to the 42 month anniversary of the closing of the Business Combination, upon achievement of a daily volume-weighted average price of at least $20.00 per share, such number of shares of the Company's common stock as equals the quotient of $20.0 million divided by the Closing Price Per Share; (2) during any such trading period prior to the six year anniversary of the closing, upon achievement of a daily volume-weighted average price of at least $35.00 per share, such number of shares of the Company's common stock as equals the quotient of $20.0 million divided by the Closing Price Per Share; and (3) during any such trading period prior to the eight year anniversary of the closing, upon achievement of a daily volume-weighted average price of at least $45.00 per share, such number of shares of the Company's common stock as equals the quotient of $20.0 million divided by the Closing Price Per Share. A total of 90.6% of (rounded to the nearest whole share) of the Earnout Shares then earned and issuable shall be issued to the Vincera Pharma stockholders on a pro-rata basis based on the percentage of the number of shares of Vincera Pharma common stock owned by them immediately prior to the closing of the Business Combination, and the remaining Earnout Shares that would otherwise have been issuable shall not be issuable to the Vincera Pharma stockholders but in lieu thereof the number of authorized shares available for issuance under the Company's 2020 Stock Incentive Plan (the "2020 Plan") shall be automatically increased by an equivalent number of shares of the Company's common stock.

4. Bayer License Agreement

On October 7, 2020, Legacy Vincerx Pharma entered into the Bayer License Agreement, which became effective on December 23, 2020 upon the closing of the Business Combination. Pursuant to the Bayer License Agreement, Legacy Vincerx Pharma has an exclusive, worldwide, royalty-bearing license under certain Bayer patents and know-how to develop, use, manufacture, commercialize, sublicense and distribute (i) a clinical-stage and follow-on small molecule drug platform, including a P-TEFb inhibitor compound, and (ii) a preclinical stage bioconjugation platform, which includes next-generation antibody-drug conjugates and innovative small molecule drug conjugates.

Following the closing of the Business Combination, the Company paid Bayer a $5.0 million upfront license fee on January 5, 2021. As of December 31, 2022, the Company recorded a $1.0 million development milestone payable to Bayer, included within accrued liabilities, in connection with the Company's IND filing for VIP 236. Each of these milestone obligations were expensed as incurred.

If the Company achieves all of the development and commercial sales milestones for license products under the Bayer License Agreement for each of the countries and disease indications, the Company would be obligated to pay milestone payments that range from $110.0 million to up to $318.0 million per licensed product, and upon successful commercialization of at least five licensed products, the Company could be required to pay aggregate milestone payments in excess of $1 billion. In addition to milestone payments, the Company is also required to pay Bayer under the Bayer License Agreement ongoing royalties in the single digit to low double-digit percentage range on net commercial sales of licensed products.

5. Restructuring

On June 4, 2022, the board of directors of the Company approved a strategic plan to prioritize and focus its resources on certain of its enitociclib clinical studies and its next generation bioconjugation platform and streamline and realign its resources to support these prioritized studies. This plan included a reduction of the Company's full-time employees by 33% and other cost reduction measures. Affected employees were offered separation benefits, including severance payments, payments to cover premiums for continuation of healthcare coverage for a limited period and in some cases vesting acceleration on certain outstanding stock options.

The Company incurred approximately $2.5 million of severance and related expenses during 2022, which includes approximately $0.5 million of stock-based compensation expense related to the acceleration of stock options to certain affected employees.

The activity in the accrued restructuring balance, included within accrued expenses on the consolidated balance sheet, was as follows for the year ended December 31, 2022 (in thousands):

	Restructuring liabilities at January 1, 2022	Charges	Cash payments	Restructuring liabilities at December 31, 2022
Workforce reduction	$—	$2,022	$(2,022)	$—

The Company does not expect to incur additional restructuring charges or cash expenditures associated with this restructuring.

6. Fair Value Measurement

The Company's financial assets and liabilities subject to fair value measurements on a recurring basis and the level of inputs used for such measurements were as follows (amounts in thousands):

	Fair Value Measured as of December 31, 2022			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash Equivalents:				
Money market funds	$2,266	$ —	$—	$ 2,266
Commercial paper	—	4,496	—	4,496
Corporate debt securities	—	3,032	—	3,032
Short-term marketable securities:				
Commercial paper	—	15,587	—	15,587
U.S. government treasuries	1,005	—	—	1,005
U.S. government agency securities	—	16,069	—	16,069
Corporate debt securities	—	8,135	—	8,135
Total cash equivalents and marketable securities	$3,271	$47,319	$—	$50,590

There were no cash equivalents or marketable securities at December 31, 2021. The Company's Level 2 securities are valued using third-party pricing sources. The pricing services utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly. There were no transfers of assets between Level 1, Level 2, or Level 3 during the year ended December 31, 2022 and 2021.

	Fair Value Measured as of December 31, 2022			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Common stock warrant liabilities	$ —	$ —	$ 144	$ 144
Total fair value	$ —	$ —	$ 144	$ 144

	Fair Value Measured as of December 31, 2021			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Common stock warrant liabilities	$ —	$ —	$6,447	$6,447
Total fair value	$ —	$ —	$6,447	$6,447

The estimated fair value of the warrant liability for the private warrants at December 31, 2022 and 2021 was determined using Level 3 inputs. Inherent in a Monte Carlo options pricing model are assumptions related to expected stock-price volatility, expected life, risk-free interest rate and dividend yield. The Company estimates the volatility of its ordinary shares based on its historical volatility for a time period that approximates the expected remaining life of the warrants. The risk-free interest rate is based on the U.S. Treasury zero-coupon yield curve on the grant date for a maturity similar to the expected remaining life of the warrants. The dividend rate is based on the historical rate, which the Company anticipates to remain at zero. There were no changes to the number of private warrants underlying the Level 3 financial instruments during the year ended December 31, 2022. There were no transfers between Level 1, 2, or 3 during the years ended December 31, 2022 and 2021.

The following table presents changes in Level 3 liabilities measured at fair value for the year ended December 31, 2022 and 2021. Both observable and unobservable inputs were used to determine the fair value of positions that the Company has classified within the Level 3 category. Unrealized gains and losses associated with liabilities within the Level 3 category include changes in fair value that were attributable to both observable (e.g., changes in market interest rates) and unobservable (e.g., changes in unobservable long-dated volatilities) inputs (in thousands).

	Warrant Liability
Balance – January 1, 2021	**$ 32,308**
Reclassification of warrant liabilities due to warrant exercises	(2,503)
Change in fair value	(23,358)
Balance – December 31, 2021	**6,447**
Change in fair value	(6,303)
Balance – December 31, 2022	**$ 144**

A summary of the weighted average (in aggregate) significant unobservable inputs (Level 3 inputs) used in measuring the Company's warrant liabilities that are categorized within Level 3 of the fair value hierarchy as of December 31, 2022 and 2021 is as follows:

	As of December 31, 2022	As of December 31, 2021
Stock price	$ 1.02	$10.19
Exercise price	$11.50	$11.50
Option term (years)	3.0	4.0
Volatility (annual)	73.7%	32.5%
Risk-free rate	4.1%	1.1%
Dividend yield (per share)	0%	0%

7. Available-For-Sale Securities

All marketable securities were considered available-for-sale at December 31, 2022. The amortized cost, gross unrealized holding gains or losses, and fair value of the Company's marketable securities by major security type at December 31, 2022 are summarized in the table below (amounts in thousands):

	December 31, 2022			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Assets:				
Short-term marketable securities:				
Commercial paper	$15,608	$—	$(21)	$15,587
U.S. government treasuries	1,007	—	(2)	1,005
U.S. government agency securities	16,105	—	(36)	16,069
Corporate debt securities	8,149	—	(14)	8,135
Total marketable securities	$40,869	$—	$(73)	$40,796

There were no cash equivalents or marketable securities at December 31, 2021. As of December 31, 2022, some of the Company's marketable securities were in an unrealized loss position. The Company determined that it did have the ability and intent to hold all marketable securities that have been in a continuous loss position until maturity or recovery, thus there has been no recognition of any other-than-temporary impairment in the year ended December 31, 2022.

8. Balance Sheet Details

Other current assets consist of the following at December 31 (in thousands):

	December 31, 2022	December 31, 2021
German grant receivable	$1,372	$—
Clinical related vendor prepayments	1,560	—
Other	369	95
	$3,301	$ 95

Property, plant and equipment, net consist of the following at December 31 (in thousands):

	December 31, 2022	December 31, 2021	Estimated Useful Life
Furniture and fixtures	$236	$236	5 years
Computers	20	22	3-5 years
Total	256	258	
Less: accumulated depreciation	(79)	(25)	
Total property, plant and equipment, net	$177	$233	

Depreciation expense was approximately $54,000 and $25,000 for the years ended December 31, 2022 and 2021, respectively.

The following table sets forth the components of accrued expenses at December 31, 2022 and 2021, respectively (in thousands):

	December 31, 2022	December 31, 2021
Accrued payroll	$ 297	$ 531
Accrued bonus	2,042	2,514
Accrued benefits	923	759
Accrued development milestone—Bayer	1,000	—
Accrued manufacturing, clinical trial and related	661	911
	$4,923	**$4,715**

9. Commitments and Contingencies

Litigation

The Company is not currently a party to any material legal proceedings and is not aware of any pending or threatened claims. From time to time, the Company may be subject to various legal proceedings and claims that arise in the ordinary course of its business activities.

Leases

On December 23, 2020, the Company entered into a five-year term lease agreement which commenced on January 1, 2021. In April and May, 2021, the lease was amended to include additional space. The annual rent expense is approximately $1.2 million.

At December 31, 2022, the Company had operating lease liabilities of approximately $3.4 million and right of use assets of approximately $3.1 million, which were included in the consolidated balance sheets.

In connection with our strategic plan and workforce reduction (see note 5), the Company has consolidated its leased office space at its corporate headquarters location. Effective July 2022, the Company has subleased substantially all of its remaining unused office space for a term of 18 months at a base rent of $50,000 per month. The Company has not been legally released from its primary obligations under the original lease and subsequent amendments and, therefore, continues to account for the original lease according to Accounting Standard Codification (“ASC”) Topic 842, “Leases.” The Company records both fixed and variable payments received from the sublessee in its consolidated statements of operations and comprehensive loss on a straight-line basis as an offset to rent expense. Such payments received in the year ended December 31, 2022 were $0.3 million. The Company also received a $50,000 deposit, recorded as a noncurrent liability in the consolidated balance sheet at December 31, 2022.

The following summarizes quantitative information about the Company's operating leases (dollars in thousands):

	For the years ended December 31, 2022	December 31, 2021
Lease cost		
Operating lease cost	$1,196	$ 619
Variable lease cost	—	—
Total operating lease expense	$1,196	$ 619
Other information		
Operating cash flows from operating leases	$1,048	$ 380
Right-of-use assets obtained in exchange for operating lease liabilities	$ —	$4,264
Weighted-average remaining lease term—operating leases	2.9	3.9
Weighted-average discount rate—operating leases	8%	8%

As of December 31, 2022, future minimum payments during the next three years are as follows (in thousands):

Year ended December 31, 2023	$1,261
Year ended December 31, 2024	1,284
Year ended December 31, 2025	1,336
Total	3,881
Less present value discount	(445)
Operating lease liabilities included in the Consolidated Balance Sheet at December 31, 2022	$3,436

10. Stockholders' Equity

The Company's Certificate of Incorporation authorizes the issuance of 120,000,000 shares of common stock, $0.0001 par value per share and 30,000,000 shares of undesignated preferred stock, $0.0001 par value per share. As of December 31, 2022 and 2021, there were 21,242,884 shares and 21,057,560 shares of common stock outstanding, respectively, and no shares of preferred stock outstanding.

On April 5, 2021, the Company announced that it would redeem all of its public warrants to purchase shares of the Company's common stock that were issued under the Warrant Agreement, dated March 5, 2020, by and between the Company and Continental Stock Transfer & Trust Company, as warrant agent, as part of the units sold in the Company's initial public offering, that remained outstanding and unexercised on May 5, 2021, the redemption date, at a redemption price of $0.01 per public warrant. In addition to the $6.1 million of cash received on April 1, 2021 from the exercise of public warrants in March 2021, prior to the redemption notice, the Company received additional proceeds of approximately $31.4 million from the exercise of additional public warrants during the redemption period. Prior to the redemption date, the units were each separated into one share of common stock and one public warrant. Pursuant to the redemption, a total of 40,491 public warrants were unexercised as of the redemption date and redeemed by the Company at the redemption price of $0.01 per public warrant.

During the year ended December 31, 2021, 275,000 private warrants were exercised for approximately $3.2 million. No private warrants were exercised during the year ended December 31, 2022.

In September 2021, the Company completed a private placement of 3.5 million shares of common stock at an offering price of $14.50 per share and raised proceeds of approximately $47.4 million, net of transaction costs of approximately $3.3 million, respectively.

During the years ended December 31, 2022 and 2021, 183,366 shares and 36,485 shares, respectively, were issued pursuant to the Company's Employee Stock Purchase Program ("ESPP") (see Note 11) for approximately $278,000 and $351,000 in proceeds, respectively.

Restricted Shares

Between July and August 2019, Legacy Vincera Pharma issued 471,850 shares (826,510 shares prior to the effects of the Merger) of restricted stock at par value to certain management persons. All amounts owed for the issuance of these restricted shares were settled in cash in July 2020. The grant date fair value of this restricted stock was approximately $6,000.

In May 2020, Legacy Vincera Pharma issued an additional 173,552 shares (304,000 shares prior to the effects of the Merger) of restricted stock at a fair value of $0.07 per share in exchange for services. Pursuant to these restricted share agreements, the term vesting represents the expiration of the Company's repurchase right for the underlying shares. As of December 31, 2022, there was approximately $5,000 of unrecognized stock-based compensation related to restricted stock that will be amortized in 1.4 years.

A summary of restricted stock activity for the years ended December 31, 2022 and 2021 is presented below:

	Number of Shares	Weighted Average Grant Date Fair Value per Share
Nonvested at January 1, 2021	**361,168**	**$0.036**
Vested	(178,482)	—
Nonvested at December 31, 2021	**182,686**	**$0.045**
Vested	(115,684)	—
Nonvested at December 31, 2022	**67,002**	**$0.065**

Warrants

As of December 31, 2022, there were 3,295,000 private warrants to purchase common stock outstanding. After the redemption described above, no public warrants remained outstanding at December 31, 2021.

The private warrants are identical to the previously outstanding public warrants except that (i) each private warrant is exercisable for one share of common stock at an exercise price of $11.50 per share and (ii) such private warrants will be exercisable for cash (even if a registration statement covering the shares of common stock issuable upon exercise of such private warrants is not effective) or on a cashless basis, at the holder's option (except with respect to 500,000 of the private warrants held by Rosedale Park, LLC and 500,000 of the private warrants held by LifeSci Holdings LLC, which were amended to remove the cashless exercise provision), and will not be redeemable by the Company (except with respect to 500,000 of the private warrants held by Rosedale Park, LLC and 500,000 of the private warrants held by LifeSci Holdings LLC, which were amended to include a redemption provision substantially identical to that of the public warrants; provided, however, that such redemption rights may not be exercised during the first 12 months following the closing of the Business Combination unless the last sales price of the Company's common stock has been equal to or greater than $20.00 per share for any 20 trading days within a 30 trading day period ending on the third business day prior to the date on which notice of redemption is given), in each case so long as they are still held by the initial purchasers or their affiliates. The private warrants purchased by Rosedale Park, LLC, will expire on March 5,

2025, provided that once the private warrants are not beneficially owned by Chardan Capital Markets, LLC or any of its related persons anymore, the private warrants may not be exercised five years following the completion of the Business Combination.

The previously outstanding public warrants and the private warrants issued to LifeSci Holdings LLC that were amended as described above were determined to be equity classified in accordance with ASC 815, Derivatives and Hedging. The remaining private warrants were determined to be liability classified in accordance with ASC 815, Derivatives and Hedging (see note 6).

11. Stock-Based Compensation

Equity Incentive Plans

In connection with the Business Combination, the stockholders approved the 2020 Plan, which became effective upon the closing of the Business Combination on December 23, 2020. As of December 31, 2022, the Company had 4,540,966 shares of common stock reserved for issuance under the 2020 Plan.

The 2020 Plan allows for the grant of stock options and rights to acquire restricted stock to employees, directors and consultants of the Company. The terms and conditions of specific awards are set at the discretion of the Company's board of directors. Options granted under the 2020 Plan expire no later than 10 years from the date of grant. Unvested common shares obtained upon early exercise of options are subject to repurchase by the Company at the original issue price.

Stock option activity under the Plan is as follows (amounts in thousands, except per share amount):

	Stock Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Outstanding at January 1, 2021	1,048	$19.00	10.0	$—
Options granted	2,367	18.62	—	—
Options cancelled	(7)	19.00	—	—
Outstanding at December 31, 2021	3,408	18.74	9.2	—
Options granted	2,509	3.30	—	—
Options exercised	(2)	0.82	—	—
Options cancelled	(1,562)	15.89	—	—
Outstanding at December 31, 2022	4,353	$10.87	8.6	$125
Options vested and exercisable at December 31, 2022	1,973	$16.71	7.8	$ 5

Stock-based compensation expense is based on the grant-date fair value. The Company recognizes compensation expense for all stock-based awards on a straight-line basis over the requisite service period of the awards, which is generally the option vesting term of either two or three years.

The Company recognized stock-based compensation of approximately $12.4 million and $23.3 million during the year ended December 31, 2022 and 2021, respectively.

As of December 31, 2022, the Company had stock-based compensation of approximately $5.2 million related to unvested stock options not yet recognized that are expected to be recognized over an estimated weighted average period of 0.9 years.

The following weighted average assumptions were used as inputs to the Black-Scholes option valuation model in determining the estimated grant-date fair value of the Company's stock options granted during the year ended December 31, 2022 and 2021:

	For the years ended December 31,	
	2022	2021
Exercise price	$3.30	$18.62
Expected term (years)	5.8	5.9
Volatility (annual)	85.1%	76.3%
Risk-free rate	2.8%	0.9%
Dividend yield (per share)	0%	0%

Total stock-based compensation expense recognized in the accompanying consolidated statements of operations and comprehensive loss for stock option awards is as follows (amounts in thousands):

	For the years ended December 31,	
	2022	2021
Research and development	$ 7,303	$14,988
General and administrative	4,689	8,325
Restructuring	447	—
Total stock-based compensation expense	**$12,439**	**$23,313**

Employee Stock Purchase Plan

The Company's 2021 Employee Stock Purchase Plan (the "ESPP") became effective in May 2021 upon stockholder approval and is intended to qualify as an "employee stock purchase plan" under Section 423 of the Internal Revenue Code. 200,000 of our authorized but unissued or reacquired shares of common stock have been reserved for issuance under the ESPP, plus an additional number of shares to be reserved annually on the first day of each fiscal year from January 1, 2022 through January 1, 2031, equal to the least of (i) one percent (1%) of the outstanding shares of the Company's common stock on such date, (ii) 500,000 shares, or (iii) a lesser amount determined by the compensation committee or the Company's board.

The ESPP allows eligible employees to purchase shares of the Company's common stock at a discount of up to 15% of their eligible compensation through payroll deductions, subject to any plan limitations. The Company's ESPP consists of a series of offerings of purchase rights to eligible employees, each with a duration of not more than 12 months and purchase dates every six months. The purchase price cannot, under the terms of the ESPP, be less than 85% of the fair market value per share of the Company's common stock on either the offering date or on the purchase date, whichever is less. If the fair market value of a share of the Company's common stock on any purchase date within a particular offering period is less than or equal to the fair market value on the start date of that offering period, then the offering period will automatically terminate and the employees in that offering period will automatically be transferred and enrolled in a new offering period which will begin on the next day following such purchase date.

As of December 31, 2022, 190,724 shares of common stock were reserved for future issuance under the ESPP. Shares issued under the ESPP were 183,366 and 36,485 shares for the years ended December 31, 2022 and 2021, respectively. The Company recorded approximately $278,000 and $176,000 of stock-based compensation expense for the years ended December 31, 2022 and 2021, respectively, related to the ESPP.

12. Net Loss per Share Applicable to Common Stockholders

Basic loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding during the reporting period. Diluted loss per common share is computed similarly to basic loss

per common share except that it reflects the potential dilution that could occur if dilutive securities or other obligations to issue common stock were exercised or converted into common stock.

The following table sets forth the computation of loss per share for the years ended December 31, 2022 and 2021, respectively (amounts in thousands, except per share number):

	For the years ended December 31,	
	2022	2021
Numerator:		
Net loss	$(65,367)	$(39,306)
Denominator:		
Weighted average common shares outstanding, basic and diluted	21,029	17,176
Net loss per common share, basic and diluted	$ (3.11)	$ (2.29)

The following table presents the potential common stock outstanding that was excluded from the computation of diluted net loss per share of common stock as of the periods presented because including them would have been antidilutive:

	For the years ended December 31,	
	2022	2021
Options outstanding	4,353	3,408
Warrants	3,295	3,295
Total	7,648	6,703

13. Income Taxes

The Company has no provision for income taxes for the year ended December 31, 2022 and 2021. The Company has no current tax expense from losses and no deferred expense from the valuation allowance.

Income (loss) before provision for income taxes consisted of the following (amounts in thousands):

	For the Year Ended December 31,	
	2022	2021
United States	$(61,091)	$(39,394)
International	(4,276)	88
	$(65,367)	$(39,306)

The effective tax rate of the Company's provision (benefit) for income taxes differs from the federal statutory rate as follows:

	For the Year Ended December 31,	
	2022	2021
Statutory federal income tax rate	21.0%	21.0%
State taxes, net of federal tax benefit	0.7%	(1.0%)
Change in fair value of warrant liabilities	2.0%	12.4%
Research and development	(0.7%)	1.4%
Other	(0.1%)	(1.2%)
Change in valuation allowance	(22.9%)	(32.6%)
Income taxes provision (benefit)	0.0%	0.0%

Significant components of the Company's net deferred tax assets as of December 31, 2022 and 2021, are as follows (amounts in thousands):

	As of December 31,	
	2022	2021
Deferred tax assets:		
Net operating loss	$ 9,639	$ 4,035
Stock-based compensation	6,620	5,164
Depreciation and amortization	4,198	4,723
Capitalized research and development	7,314	—
Research and development credit	1,635	891
Accruals and reserves	471	575
Lease liability	722	877
Total deferred income tax assets	30,599	16,265
Less: Valuation allowances	(29,955)	(15,436)
Deferred tax assets, net of valuation allowances	$ 644	$ 829
Deferred tax liabilities:		
Right of use asset	(644)	(829)
Total deferred income tax liabilities	$ (644)	$ (829)
Net deferred taxes	$ —	$ —

ASC 740 requires that the tax benefit of net operating losses, temporary differences and credit carryforwards be recorded as an asset to the extent that management assesses that realization is "more likely than not." Realization of the future tax benefits is dependent on the Company's ability to generate sufficient taxable income within the carryforward period. Because of the Company's recent history of operating losses, management believes that recognition of the deferred tax assets arising from the above-mentioned future tax benefits is currently not likely to be realized and, accordingly, has provided a valuation allowance. The Company's valuation allowance increased by $14.5 million and $12.4 million for the years ended December 31, 2022 and 2021, respectively.

Effective for tax years beginning after December 31, 2021, taxpayers are required to capitalize any expenses incurred that are considered incidental to research and experimentation (R&E) activities under IRC Section 174. While taxpayers historically had the option of deducting these expenses under IRC Section 174, the December 2017 Tax Cuts and Jobs Act mandates capitalization and amortization of R&E expenses for tax years beginning after December 31, 2021. Expenses incurred in connection with R&E activities in the U.S. must be amortized over a five-year period and over a fifteen-year period if incurred outside the U.S. R&E activities are broader in scope than qualified research activities considered under IRC Section 41 (relating to the research tax credit). For the year ended December 31, 2022, the Company performed an analysis based on available guidance and determined that it will continue to be in a loss position even after the required capitalization and amortization of its R&E expenses. The Company will continue to monitor this issue for future developments, but it does not expect R&E capitalization and amortization to require it to pay cash taxes now or in the near future.

At December 31, 2022, the Company had federal and state net operating loss carryforwards of approximately $38.4 million and $0.7 million, respectively. The federal net operating loss carryforwards can be carried forward indefinitely, with certain limitations. A portion of the state net operating loss carryforwards will expire beginning in 2039, if not utilized.

As of December 31, 2022, the Company also has Federal and California research and development credits of $1.8 million and $1.0 million, respectively. The federal tax credit carryforwards will expire beginning in 2039, if not utilized. The state tax credit carryforwards do not expire.

The following table summarizes activity related to the Company's gross unrecognized tax benefits (amounts in thousands):

	Total
Balance as of December 31, 2020	$ —
Increase/decrease due to prior year positions	—
Increase/decrease due to current year positions	518
Balance as of December 31, 2021	518
Increase/decrease due to prior year positions	(164)
Increase/decrease due to current year positions	625
Balance as of December 31, 2022	$ 979

The unrecognized tax benefits, if recognized, would not have an impact on the Company's effective tax rate due to the valuation allowance. The Company does not expect a significant change to its unrecognized tax benefits over the next twelve months. The Company files income tax returns in the United States, California and Germany jurisdictions and is not currently under examination by federal, state or local taxing authorities for any open tax years. The tax years 2019 through 2022 remain open to examination by the major taxing authorities. The Company records interest related to uncertain tax positions as interest, and any penalties are recorded as income tax expense in its consolidated statements of operations and comprehensive loss.

Utilization of net operating losses and tax credit carryforwards may be limited by the "ownership change" rules, as defined in Section 382 of the Internal Revenue Code (any such limitation, a "Section 382 limitation"). Similar rules may apply under state tax laws. The Company has not performed an analysis to determine whether an "ownership change" occurred from inception to December 31, 2022. If a change in ownership were to have occurred, additional net operating loss and tax credit carryforwards could be eliminated or restricted. If eliminated, the related asset would be removed from the deferred tax asset schedule with a corresponding reduction in the valuation allowance.

ASC 740-10, "Income Taxes", prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of uncertain tax positions taken or expected to be taken in the Company's income tax return and also provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition.

On March 27, 2020 and December 27, 2020, the United States enacted the Coronavirus Aid, Relief, and Economic Security (CARES) Act and the Consolidated Appropriation Act (CAA), respectively, which contain among other matters, numerous income tax provisions. Some of these tax provisions are expected to be effective retroactively for years ending before the date of enactment. The Company has evaluated the current legislation and does not anticipate the CARES Act or the CAA to have a material impact on its consolidated financial statements.

On June 29, 2020, California's Governor Newsom signed AB85 suspending California net operating loss utilization and imposing a cap on the amount of business incentives tax credits (R&D credit) for tax years 2020-2022. Given an expected tax loss for 2022, the suspension does not have a material impact on the Company's provision for income taxes in its consolidated financial statements.

In January 2018, the FASB released guidance on the accounting for tax on the global intangible low-taxed income ("GILTI") provisions of the Tax Cuts and Jobs Act of 2017. The GILTI provisions impose a tax on foreign income in excess of a deemed return on tangible assets of foreign corporations. The guidance indicates that either accounting for deferred taxes related to GILTI inclusions or treating any taxes on GILTI inclusions as period cost are both acceptable methods subject to an accounting policy election. The Company has elected to treat any potential GILTI inclusions as a period cost.

ITEM 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

Not applicable.

ITEM 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as such term is defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, or the Exchange Act, that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognized that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Our disclosure controls and procedures have been designed to meet reasonable assurance standards. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure controls and procedures 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.

Based on their evaluation as of the end of the period covered by this Annual Report on Form 10-K, our Chief Executive Officer (our principal executive officer) and Chief Financial Officer (our principal financial officer) have concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining a system of internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP. All internal control systems, no matter how well designed, have inherent limitations.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, under the oversight of our board of directors, we evaluated the effectiveness of our internal control over financial reporting as of December 31, 2022, the last day of our fiscal year. This evaluation was based on the criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our assessment, management has concluded that our internal control over financial reporting was effective as of the end of the fiscal year to provide reasonable assurances regarding the reliability of financial reporting and the preparation of financial statements for external reporting purposes in accordance with GAAP.

Changes in Internal Control over Financial Reporting

Based on the foregoing assessment, our management, including our Chief Executive Officer and Chief Financial Officer, has concluded that there has been no change in our internal control over financial reporting that occurred during the quarter ended December 31, 2022 and that there was no change during such period that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. Other Information.

None.

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

Not applicable.

PART III

ITEM 10. Directors, Executive Officers and Corporate Governance.

The information required by this item with respect to directors is incorporated by reference from the information under the caption "Election of Directors," contained in our proxy statement to be filed with the Securities and Exchange Commission no later than 120 days from the end of our fiscal year ended December 31, 2022 in connection with the solicitation of proxies for our 2023 Annual Meeting of Stockholders (the "Proxy Statement"). Certain information required by this item concerning executive officers is set forth in the Proxy Statement under the caption "Executive Officers" and is incorporated herein by reference.

There have been no material changes to the procedures by which stockholders may recommend nominees to our board of directors.

Item 405 of Regulation S-K calls for disclosure of any known late filing or failure by an insider to file a report required by Section 16(a) of the Exchange Act. To the extent disclosure for delinquent reports is being made, it can be found under the caption "Delinquent Section 16(a) Reports" in the Proxy Statement and is incorporated herein by reference.

Our board of directors has adopted a code of business conduct and ethics applicable to all employees of the Company. The code of business conduct and ethics is posted on our website www.vincerx.com. The code of business conduct and ethics can only be amended by the approval of a majority of our board of directors. Any waiver to the code of business conduct and ethics for an executive officer or director may only be granted by our board of directors or our nominating and corporate governance committee and must be timely disclosed as required by applicable law. We have implemented whistleblower procedures that establish formal protocols for receiving and handling complaints from employees. Any concerns regarding accounting or auditing matters reported under these procedures will be communicated promptly to our audit committee.

To date, there have been no waivers under our code of business conduct and ethics. We intend to disclose future amendments to certain provisions of our code of business conduct and ethics or waivers of such code granted to executive officers and directors on our website at www.vincerx.com within four business days following the date of such amendment or waiver. Stockholders may request a free copy of our code of business conduct and ethics by contacting Vincerx Pharma, Inc., Attention: General Counsel & Chief Legal Officer, 260 Sheridan Avenue, Suite 400, Palo Alto, CA 94306. None of the materials on, or accessible through, our website is part of this report or incorporated by reference herein.

Additionally, our board of directors has adopted a code of ethics for senior financial officers applicable to our Chief Executive Officer and Chief Financial Officer as well as other key management employees addressing ethical issues. Any amendments or waivers of the code of ethics for senior financial officers shall be disclosed promptly as required by law. To date, there have been no waivers under our code of ethics for senior financial officers.

ITEM 11. Executive Compensation.

The information required by this item is incorporated by reference from the information under the headings "Election of Directors—Director Compensation," "Election of Directors—Director Compensation Arrangements," and "Executive Compensation" contained in the Proxy Statement.

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

The information required by this item is incorporated by reference to the disclosure appearing under the headings "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" contained in the Proxy Statement.

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

The information required by this item is incorporated by reference from the information under the headings "Election of Directors—Voting Agreement," "Election of Directors—Director Independence," "Election of Directors—Corporate Governance," and "Election of Directors—Certain Relationships and Related Transactions" contained in the Proxy Statement.

ITEM 14. Principal Accountant Fees and Services.

The information required by this item is incorporated by reference from the information under the caption "Ratification of Appointment of Independent Registered Public Accounting Firm" contained in the Proxy Statement.

PART IV

ITEM 15. Exhibit and Financial Statement Schedules.

(a) Documents filed as part of this report

1. Financial Statements:

Reference is made to the Index to Financial Statements of Vincerx Pharma, Inc. included in Item 8 of Part II of this report.

2. Financial Statement Schedules

All schedules have been omitted because they are not required, not applicable, or the required information is included in the financial statements or notes thereto.

3. Exhibits

See Item 15(b) below. Each management contract or compensatory plan or arrangement required to be filed has been identified.

(b) Exhibits

Exhibit No.	Description
2.1+	Merger Agreement by and among LifeSci Acquisition Corp., LifeSci Acquisition Merger Sub Inc., Vincera Pharma, Inc. and Raquel E. Izumi, as representative of the stockholders of Vincera Pharma, Inc., dated September 25, 2020 (incorporated by reference to Exhibit 2.1 to the Current Report on Form 8-K filed on December 30, 2020).
3.1	Second Amended and Restated Certificate of Incorporation, as amended by the Certificate of Amendment (incorporated by reference to Exhibit 3.1 to the Registration Statement on Form S-1 (File No. 333-252589) filed on January 29, 2021).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on April 5, 2021).

Exhibit No.	Description
4.1	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Registration Statement on Form S-1 (File No. 333-252589) filed on January 29, 2021).
4.2	Form of Warrant (incorporated by reference to Exhibit 4.2 to the Registration Statement on Form S-1 (File No. 333-252589) filed on January 29, 2021).
4.3	Warrant Agreement by and between LifeSci Acquisition Corp. and Continental Stock Transfer & Trust Company, dated March 5, 2020 (incorporated by reference to Exhibit 4.1 to the Quarterly Report on Form 10-Q filed on November 10, 2020).
4.4	Amended and Restated Registration and Stockholder Rights Agreement by and among the Company and certain stockholders of the Company, dated December 23, 2020 (incorporated by reference to Exhibit 4.4 to the Current Report on Form 8-K filed on December 30, 2020).
4.5	Voting and Support Agreement by and among the Company and certain stockholders of the Company, dated December 23, 2020 (incorporated by reference to Exhibit 4.5 to the Current Report on Form 8-K filed on December 30, 2020).
4.6	Registration Rights Agreement by and among the Company and the Investors party thereto, dated September 15, 2021 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on September 16, 2021).
4.7	Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934 (incorporated by reference to Exhibit 4.7 to the Annual Report on Form 10-K for the year ended December 31, 2021).
4.8	Form of Indenture relating to debt securities (incorporated by reference to Exhibit 4.1 to the registration Statement on Form S-3 (File No. 333-262239) filed on January 19, 2022).
10.1#	Form of Indemnification Agreement by and between the Company and its directors and officers (incorporated by reference to Exhibit 10.1 to the Registration Statement on Form S-1 (File No. 333-252589) filed on January 29, 2021).
10.2#	Vincerx Pharma, Inc. 2020 Stock Incentive Plan (incorporated by reference to Exhibit 10.2 to the Registration Statement on Form S-1 (File No. 333-252589) filed on January 29, 2021).
10.3#	Forms of Stock Option Agreement, Notice of Exercise, Stock Option Grant Notice, Restricted Stock Unit Agreement, and Restricted Stock Agreement under the Vincerx Pharma, Inc. 2020 Stock Incentive Plan (incorporated by reference to Exhibit 10.3 to the Registration Statement on Form S-1 (File No. 333-252589) filed on January 29, 2021).
10.4#	Executive Employment Agreement by and between the Company and Dr. Ahmed M. Hamdy, dated December 23, 2020 (incorporated by reference to Exhibit 10.4 to the Current Report on Form 8-K filed on December 30, 2020).
10.5#	Executive Employment Agreement by and between the Company and Dr. Raquel E. Izumi, dated December 23, 2020 (incorporated by reference to Exhibit 10.5 to the Current Report on Form 8-K filed on December 30, 2020).
10.6#	Executive Employment Agreement by and between the Company and Alexander A. Seelenberger, dated December 23, 2020 (incorporated by reference to Exhibit 10.6 to the Current Report on Form 8-K filed on December 30, 2020).
10.7#	Executive Employment Agreement by and between the Company and Tom C. Thomas, dated January 27, 2021 (incorporated by reference to Exhibit 10.8 to the Annual Report on Form 10-K for the year ended December 31, 2020).

Exhibit No.	Description
10.8#	Vincerx Pharma, Inc. 2021 Employee Stock Purchase Plan (incorporated by reference to Exhibit 99.1 to the Registration Statement on Form S-8 (File No. 333-257042) filed on June 11, 2021).
10.9*	License Agreement by and among Vincera Pharma, Inc., Bayer Aktiengesellschaft and Bayer Intellectual Property GmbH, dated October 7, 2020 (incorporated by reference to Exhibit 10.7 to the Current Report on Form 8-K filed on December 30, 2020).
10.10	Standard Industrial/Commercial Multi-Tenant Lease – Gross Agreement by and between the Vincera Pharma, Inc. and Hohbach Realty Company Limited Partnership, dated November 18, 2020 (incorporated by reference to Exhibit 10.9 to the Current Report on Form 8-K filed on December 30, 2020).
21.1	Subsidiaries of the Company (incorporated by reference to Exhibit 21.1 to the Current Report on Form 8-K filed on December 30, 2020).
23.1	Consent of independent registered public accounting firm.
24.1	Power of Attorney (included on the signature page hereof).
31.1	Principal Executive Officer's Certifications Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Principal Financial Officer's Certifications Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1†	Certification Pursuant to 18 U.S.C. § 1350 (Section 906 of Sarbanes-Oxley Act of 2002).
32.2†	Certification Pursuant to 18 U.S.C. § 1350 (Section 906 of Sarbanes-Oxley Act of 2002).
101.INS	Inline XBRL Instance 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)

+ The schedules and exhibits to this agreement have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the SEC upon request.

# Indicates management contract or compensatory plan or arrangement.

* Portions of this exhibit have been omitted in accordance with Item 601(b)(10)(iv) of Regulation S-K.

† In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release No. 34-47986, the certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Form 10-K and will not be deemed

"filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act"), or deemed to be incorporated by reference into any filing under the Exchange Act or the Securities Act of 1933 except to the extent that the registrant specifically incorporates it by reference.

(c) Financial Statement Schedules

Reference is made to Item 15(a)(2) above.

ITEM 16. Form 10-K Summary.

Not applicable.

SIGNATURES

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

VINCERX PHARMA, INC.

/s/ Dr. Ahmed M. Hamdy

Name: Dr. Ahmed M. Hamdy
Title: Chief Executive Officer

Date: March 28, 2023

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENT, that each person whose signature appears below constitutes and appoints Dr. Ahmed M. Hamdy, Dr. Raquel E. Izumi and Alexander A. Seelenberger, and each of them, his or her true and lawful attorneys-in-fact, each with full power of substitution, for him or her in any and all capacities, to sign any amendments to this report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact or their substitute or substitutes may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons, on behalf of the registrant on the dates and the capacities indicated.

Signature	Title	Date
/s/ Dr. Ahmed M. Hamdy Dr. Ahmed M. Hamdy	Chief Executive Officer and Chairman (Principal Executive Officer)	March 28, 2023
/s/ Alexander A. Seelenberger Alexander A. Seelenberger	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 28, 2023
/s/ Laura I. Bushnell Laura I. Bushnell	Director	March 28, 2023
/s/ Dr. Brian J. Druker Dr. Brian J. Druker	Director	March 28, 2023
/s/ Dr. Raquel E. Izumi Dr. Raquel E. Izumi	Director	March 28, 2023
/s/ Dr. John H. Lee Dr. John H. Lee	Director	March 28, 2023
/s/ Francisco D. Salva Francisco D. Salva	Director	March 28, 2023
/s/ Dr. Ruth E. Stevens Dr. Ruth E. Stevens	Director	March 28, 2023