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, 2023

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, 2023) was approximately $23.0 million.

As of March 26, 2024, there were 21,413,389 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2024 Annual Meeting of Stockholders, which will be filed with the United States Securities and Exchange Commission within 120 days of December 31, 2023, 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;
- the attributes of, and our ability to develop or commercialize, our product candidates;
- the strength of our pipeline, product candidates, VersAptx platform and management team;
- the expected results and timing of clinical trials and nonclinical studies;
- our ability to comply with the terms of the Bayer License Agreement;
- our future capital requirements and sufficiency of available cash, including our expected cash runway, timing of those requirements, and sources and uses of cash;
- our ability to obtain funding for our operations and continue as a going concern;
- developments and expectations 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;
- 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 and product development milestones;
- changes in the assumptions underlying our expectations regarding our future business or business model;
- our ability to develop, manufacture, and commercialize product candidates;
- our ability to raise capital and continue as a going concern;
- general economic, financial, legal, political, and business conditions and changes in domestic and foreign markets;
- changes in applicable laws or regulations, including the impact of the Inflation Reduction Act of 2022 and potential legislation restricting the use of foreign third-party service providers;

- the impact of natural disasters, including climate change, and the impact of health pandemics and epidemics on our business;
- the size and growth potential of the markets for our products, and our ability to compete in those markets;
- market acceptance of our planned products;
- the effects of other economic, business, or competitive factors, including the impact of inflation and the wars in Ukraine and Israel; and
- other risks and uncertainties set forth in this report in the section entitled "Risk Factors."

Given these and other risks and uncertainties described in this report, 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 2024 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.

- "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.
- "DLBCL" means diffuse large B-cell lymphoma.
- "DH-DLBCL" means double-hit DLBCL (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.
- "IL3RA" means Interleukin 3 receptor subunit alpha.
- "HIPAA" means the Health Insurance Portability and Accountability Act.
- "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.

- "MYC" means a family of regulator genes and proto-oncogenes that code for transcription factors.
- "NDA" means a new drug application.
- "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, CellTrapper®, and VersAptx™ are our trademarks or registered trademarks. This report also contains 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 VIP236, VIP943, VIP924, enitociclib, the VersAptx platform, and our other current product candidates and technologies that incorporate such intellectual property, raise capital, or continue our operations.
- We are substantially dependent on the success of VIP236, VIP943, and enitociclib, 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.
- 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.
- 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 subsequent or final data.

- We have incurred net losses since inception and expect to continue to incur significant net losses for the foreseeable future, and there can be no assurance we will be able to raise capital.
- 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 and may not be able to continue as a going concern.
- 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.
- 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, and we may not be able to raise additional capital or enter into strategic alliances at levels sufficient to pay these amounts when due.
- 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) the right to receive Earnout Shares under certain conditions following 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.

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.

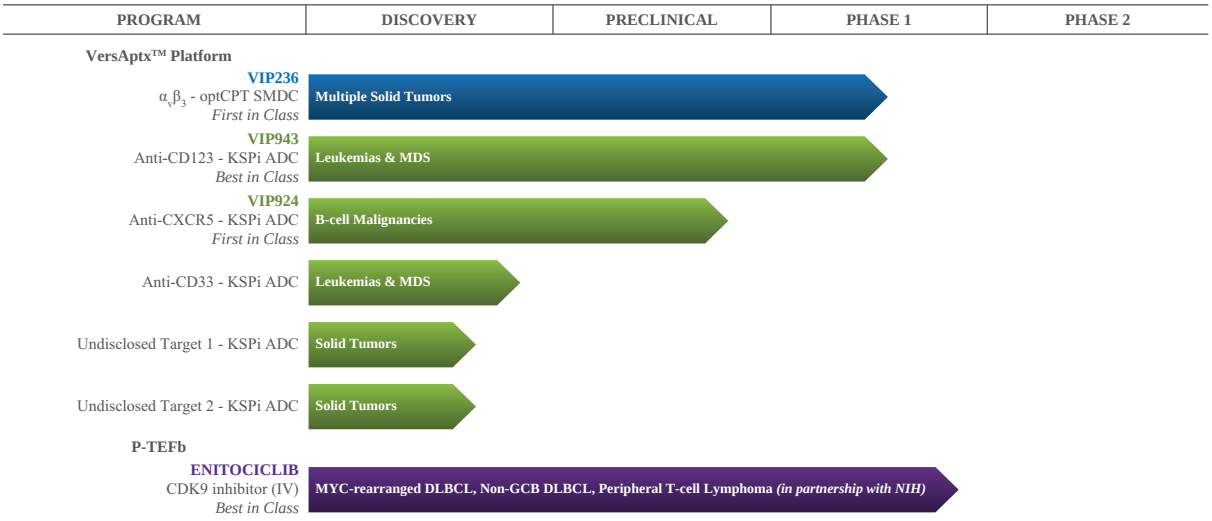
We have a versatile and adaptable, next generation bioconjugation platform, called VersAptx. The modular nature of this innovative platform allows us to combine targeting, linker, and payload technologies to develop bespoke bioconjugates to address different cancer biologies. The VersAptx platform has the following features:

- Antibodies and small molecules that target different tumor antigens, including non-internalizing targets
- Linkers designed to:
  - reduce non-specific release of the payload
  - cleave intracellularly or extracellularly
  - conjugate to single or multiple payloads

- Payloads designed to:
  - reduce permeability using our CellTrapper™ technology to ensure accumulation in cancer cells
  - increase permeability with low efflux for release in the TME.

The VersAptx platform allows us to optimize these technologies to a specific target and develop bioconjugates designed to address the safety and efficacy challenges of first-generation bioconjugates.

The following graphic summarizes our diverse pipeline:



Our accomplished management team, with collective experience of over 120 years in oncology, brings a proven track record in successful drug development, approvals, and value creation. Drawing talent from leading companies such as Pharmacyclics LLC, Acerta Pharma LLC, AstraZeneca plc, Bayer AG, Amgen Inc., Genentech Inc., Eli Lilly and Company, and Johnson & Johnson Inc, they have significantly contributed to multiple drug approvals and blockbuster exits, including the $7B acquisition of Acerta Pharma's Calquence® by AstraZeneca and the $975M Imbruvica® partnership between Janssen Pharmaceuticals (now J&J Innovative Medicine) and Pharmacyclics.

We believe our diverse pipeline including our next-generation VersAptx platform and our management team position us to successfully develop paradigm-shifting therapies for patients.

Strategy

Our goal is to become a leading biopharmaceutical company by developing differentiated and novel therapies that are safe, effective, and well-tolerated. We seek to accomplish this goal through the implementation of the following strategy:

- Progress VIP943, VIP236, and enitociclib through clinical development and proof-of concept
- Progress VIP924 to an IND application in late 2025 or early 2026
- Leverage our next-generation VersAptx platform to expand our pipeline and collaborate with other companies to develop unique, safe, and effective ADCs and SMDCs
- Form strategic partnerships/collaborations to maximize the potential of our pipeline and VersAptx platform

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

Our Value Proposition

The VersAptx Platform

The VersAptx platform is a versatile and adaptable, next generation bioconjugation platform. The modular nature of this platform allows us to combine different targeting, linker, and payload technologies to develop unique ADCs and SMDCs that address the safety and efficacy challenges of first-generation bioconjugates.

The VersAptx platform has the following features:

Targets. We use antibodies or small molecules to target different tumor antigens. Currently, we have disclosed the following hematologic and solid tumor targets:

- **CD123:** A protein mainly produced by activated T-cells and expressed at high levels in AML, classical Hodgkin lymphoma, B-cell acute lymphoblastic leukemia (B-ALL), and MDS. Targeting CD123 allows for selective destruction of cancer cells while sparing normal cells, potentially minimizing side effects.
- **CXCR5**: A receptor that regulates chemotaxis, germinal center formation, and plasma and memory B-cell differentiation and is highly expressed on the tumor cells of DLBCL, FL, MCL, and CLL. The specific expression pattern of CXCR5 prevents general effects on the B-cell population commonly observed with other compounds in this disease area. Targeting CXCR5 can also address the issue of cancer cell masking, by preventing homing into lymphatic systems (e.g., lymph nodes), keeping the cells exposed to the treatment.
- $\alpha_v\beta_3$: A small molecule integrin binder and well-established target in solid tumors. $\alpha_v\beta_3$ is found on tumor cells and in the TME and is overexpressed in advanced and metastatic solid tumors. High expression of $\alpha_v\beta_3$ is commonly associated with poor survival prognosis.
- **CD33**: CD33 is a cell surface protein primarily found in myeloid cells and plays a crucial role in regulating immune cell activity. This protein is particularly intriguing as a target for ADCs due to its prevalence in malignant AML cells. CD33 is a validated target in AML as a monotherapy and could also prove to be safe and efficacious when combined with VIP943 by effectively targeting nearly all malignant AML cells in patients.

Linkers. Linkers designed to reduce non-specific release of the payload, cleave intracellularly or extracellularly, and conjugate to single or multiple payloads. Currently, we have disclosed the following linker technologies:

- **Legumain Linker**: A novel linker that cleaves specifically by legumain, a protein that is present and overactive inside cancer cells. The stability and mechanism of action of this linker allows for targeted payload release within tumor cells after internalization.
- **Neutrophil Elastase Linker**: A novel linker that selectively cleaves in the TME by neutrophil elastase, a protein highly expressed in the TME of advanced and metastatic solid tumors and associated with poor survival. Neutrophil elastase retains its structural integrity while circulating in the body and avoids cleavage in non-target tissues, allowing for a targeted payload release inside the TME.

Payloads. Highly potent and optimized payloads, designed to address common challenges in their class. Currently, we have disclosed the following payloads:

- **Optimized Camptothecin (CPT)**: Designed to have (i) high permeability, so it can efficiently enter cancer cells, and (ii) low efflux, so it stays in the cancer cell to inhibit topoisomerase 1—causing

DNA damage and cell death. Camptothecins are an established payload class. The structural optimization of our camptothecin is designed to address the issue of transporter effect, a common resistance mechanism seen in this payload class.

- **Kinesin Spindle Protein Inhibitor (KSPi)**: This highly potent and selective KSPi payload specifically targets the kinesin spindle protein, a protein that is essential for mitotic spindle formation and only expressed during cell division. This novel payload is designed to allow us to only target dividing cells while sparing healthy cells, effectively circumventing common side effects associated with other payload classes.

CellTrapper. Our proprietary CellTrapper technology is designed to reduce payload cellular permeability, so the released payload accumulates within the target cell. This accumulation enables precise targeting of transiently expressed KSP, thereby inducing cell death. Moreover, the inability of the released payload to diffuse through membranes ensures non-target cells remain unaffected.

Beyond the technologies described above, our research and development team continues to work on new undisclosed bioconjugation technologies for solid tumor and hematologic indications.

Improving the Safety and Efficacy of Bioconjugates

The full potential of bioconjugates has been hindered by many challenges, such as payload damage of non-dividing/non-target cells, premature payload release, and unspecific cellular uptake, each of which can result in severe adverse effects including myelosuppression, infections, and hepatotoxicity. The adaptable and modular nature of our VersAptx platform allows us to combine different targeting, linker, and payload technologies to develop unique bioconjugates, such as those in our current product pipeline, that are designed to address the safety and efficacy challenges of existing bioconjugates. Our technological advancements have been demonstrated in preclinical studies, including the following comparisons to FDA-approved bioconjugates:

- At the American Society of Hematology (ASH) 2022 Annual Meeting, we presented preclinical data demonstrating how our legumain linker + KSPi payload with CellTrapper effector chemistry improved the safety and efficacy of Mylotarg®[1] (gemtuzumab-ozogamycin), the only marketed ADC for AML.
- At the American Association for Cancer Research (AACR) 2023 Annual Meeting, we presented preclinical data for VIP236, our SMDC, demonstrating improved efficacy in patient- and cell line-derived gastric cancer models compared with ENHERTU®[2], a marketed ADC for HER2+ solid tumors.
- At the ASH 2023 Annual Meeting, we presented preclinical data for VIP924 demonstrating superior efficacy and safety compared with Polivy®[3] and Zynlonta®[4], two marketed ADCs for B-cell lymphoma.
- Recently, we demonstrated in a preclinical study the ability of our legumain linker + KSPi payload with CellTrapper effector chemistry to enhance the potency of TRODELVY®[5] and ENHERTU, two marketed ADCs, by conjugating TRODELVY's TROP2 and ENHERTU's HER2 antibodies with our effector chemistry. The results of this study, shown in the table below, demonstrated a significant improvement in the potency of both drugs, with TRODELVY potency amplified by a factor of 20 and ENHERTU potency by a factor of 8.

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1 Mylotarg™ is a trademark owned by Pfizer Inc.
2 ENHERTU® is a trademark owned by Daiichi Sankyo, Inc. and AstraZeneca LP
3 Polivy® is a trademark owned by Genentech USA, Inc.
4 Zynlonta® is a trademark owned by ADC Therapeutics SA
5 TRODELVY® is a trademark owned by Gilead Sciences, Inc.

Legumain + KSPi with CellTrapper has the Potential to Improve the Efficacy of TROP2 and HER2 ADCs

Brand Name	Substance/ Vehicle	DAR	Linker	Payload	NCI N87 IC_{50} (M)	Fold-Improved
	Isotype-ADC	5.6	Legumain	KSPi	>1.0E-06	
Trodelvy	Sacituzumab govitecan	7.6	CL2A	SN38	5.93E-09	1
	Sacituzumab-Legumain-KSPi	5.7	Legumain	KSPi	2.90E-10	20
ENHERTU	fam-Trastuzumab-Deruxtecan	8.0	Cathepsin B	Dxd	9.62E-10	1
	Trastuzumab-Legumain-KSPi	8.4	Legumain	KSPi	1.24E-10	8
	Pertuzumab-Legumain-KSPi	5.6	Legumain	KSPi	2.04E-10	

These preclinical studies underscore the potential of the VersAptx platform in developing safer and more efficacious treatment options in hematological malignancies and solid tumors.

Our Product Candidates

Antibody Drug Conjugate: VIP943 (CD123-KSPi)

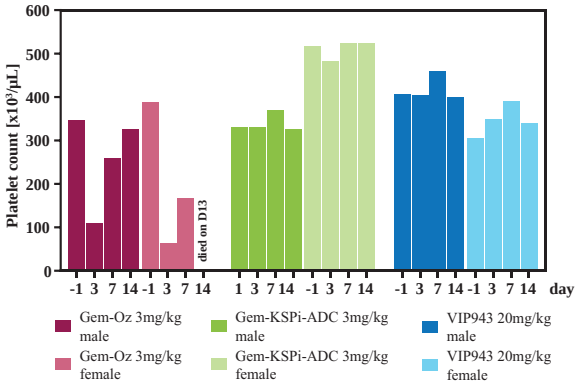
VIP943 is a potential best-in-class anti-CD123 ADC created with our VersAptx Platform. It consists of an anti-CD123 antibody, a novel legumain-cleavable linker, and a KSPi payload enhanced with our CellTrapper technology. CD123 is a protein predominantly produced by activated T-cells. In diseases like AML, B-cell acute lymphoblastic leukemia (B-ALL), classical Hodgkin lymphoma, and MDS, CD123 is expressed at elevated levels, particularly in peripheral blasts and leukemic stem cells. By employing an anti-CD123 antibody, VIP943 can selectively target cells expressing CD123 while minimizing impact on healthy cells. Our VIP943 effector chemistry (legumain linker + KSPi payload with CellTrapper) is designed to deliver improved efficacy and safety, allowing us to prolong patients' treatment duration and thereby effectively target the leukemic stem cells accountable for disease relapse.

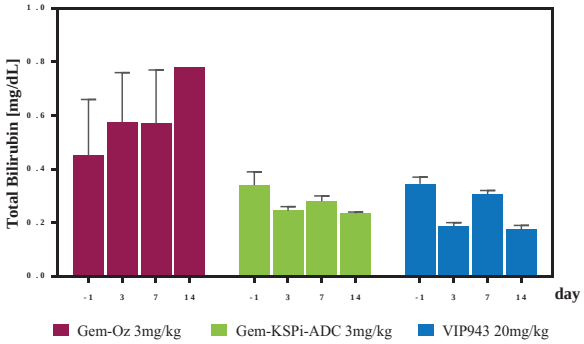
Preclinical Results

On-target selectivity and activity assays show our KSPi payload is highly selective for the kinesin spindle protein target, Eg5, versus other members of the related KIF super family. This on-target activity translates to cell cycle arrest at the G2/M phase of mitosis, resulting in cell death in AML cell lines. In vitro cytotoxicity assays show that most hematologic cell lines (n=56) are sensitive to KSPi and that DNA alterations (including common AML mutations such as TP53) did not reduce its cytotoxicity. Nonhuman primate safety and toxicokinetic studies show that repeat dosing of VIP943 in cynomolgus monkeys has good overall tolerability without the myelosuppression and hepatotoxicity seen with other ADCs. This is consistent with the favorable safety profile seen to date in the VIP943 Phase 1 dose-escalation study.

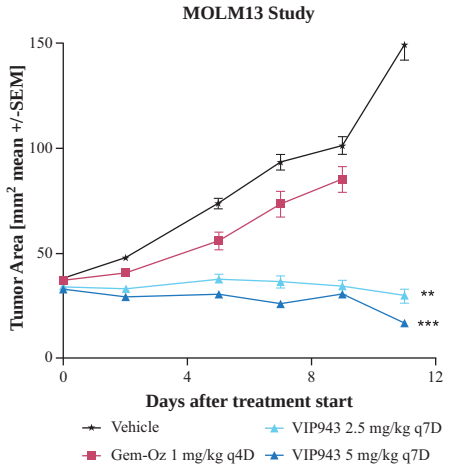
At the American Society of Hematology (ASH) 2022 Annual Meeting, we presented data for VIP943 demonstrating in monkeys the benefit of our VIP943 effector chemistry. In this safety study, we compared VIP943 to Mylotarg (gemtuzumab-ozogamycin; FDA approved ADC for AML), and to Mylotarg's anti-CD33 monoclonal antibody combined with our VIP943 effector chemistry (legumain linker + KSPi payload with CellTrapper). Following a single dose of each test agent (n=2 per group), the Mylotarg group showed a significant drop in platelet and red blood cell counts with insufficient recovery, along with a continuous decrease in white blood cells and lymphocyte. Mylotarg-treated animals also exhibited critical decreases in hemoglobin and hematocrit, indicating adverse effects. In contrast, the ADCs with our VIP943 effector chemistry showed no impact on the number of platelets or red blood cell populations. Mylotarg also led to increased liver enzymes, severely elevated total bilirubin (signifying liver toxicity), and an extreme rise in urea nitrogen (indicating kidney toxicity). These adverse events prompted euthanasia for one Mylotarg-treated monkey, while another died on

day 13. In contrast, no animals treated with ADCs using our VIP943 effector chemistry died, and all were healthy after the study's conclusion.





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 with Mylotarg. In that study, VIP943 achieved tumor regression after 2 cycles, while Mylotarg resulted in disease progression in all treated mice.



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*
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

* Measured at day 10

** P<0.01, *** P<0.001 vs vehicle

Clinical Studies

VIP943 is in a Phase 1 dose-escalation study treating patients with relapsed/refractory AML, myelodysplastic syndrome, and B-cell acute lymphoblastic leukemia who have exhausted standard therapeutic options (NCT06034275).

In September 2023, we dosed the first patient in this study. To date, we have completed dosing two cohorts and enrollment in the third cohort has started, with a total of 9 patients dosed in the study. The preliminary pharmacokinetic data from the first two cohorts show low levels of unconjugated payload in circulation, aligning with preclinical findings in nonhuman primates. Early safety data is also promising, with no patients showing dose-limiting toxicities in cohorts 1 and 2. We expect to release more details regarding the preliminary dose escalation study data on or around the 2024 European Hematology Association (EHA) Annual Meeting in June 2024.

Potential Clinical Path

We expect to expand into additional CD123-positive indications, including TP53 mutated AML, as safety and efficacy data are generated.

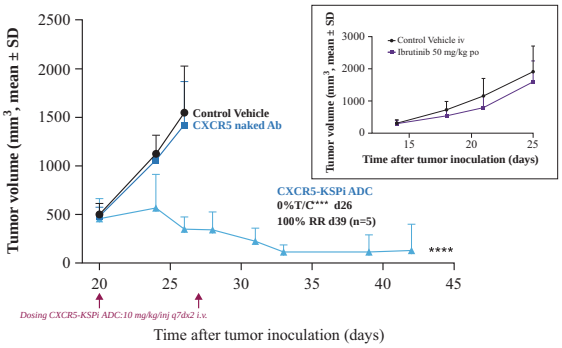
Antibody Drug Conjugate: VIP924 (CXCR5-KSPi)

VIP924 is a first-in-class anti-CXCR5 ADC created with our VersAptx platform and shares the same effector chemistry as VIP943 (legumain linker + KSPi payload with CellTrapper). CXCR5 governs crucial processes including chemotaxis, germinal center formation, and differentiation of plasma and memory B-cells. It is highly expressed on tumor cells of DLBCL, FL, MCL and CLL. As with VIP943, our VIP924 effector chemistry is designed to reduce non-specific release and uptake of the payload and ensure payload accumulation in cancer cells.

Preclinical Results

In preclinical studies, VIP924 induced sustained tumor regression in MCL and DLBCL models, including ibrutinib-refractory MCL cell-derived models, with only 1 or 2 doses.

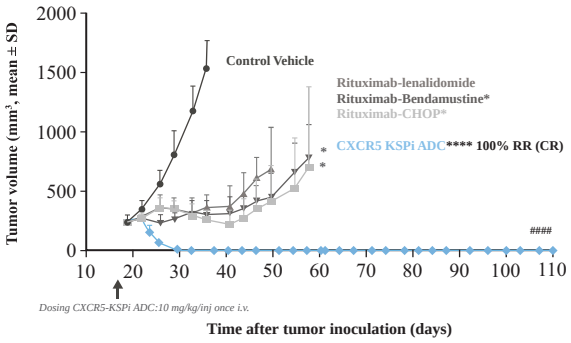
VIP924 Is Active in Ibrutinib-Refractory MCL In Vivo Model



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

**** P=0.0001 vs vehicle. Tumor volumes on day 26.

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

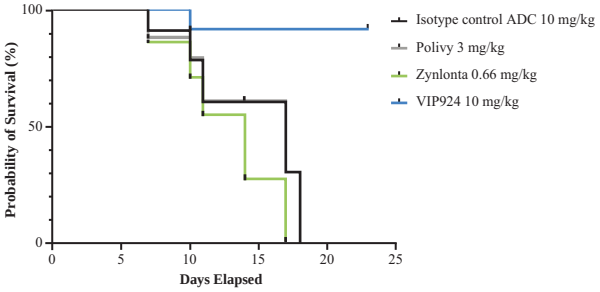


- Complete regression with single dose of VIP924 in CXCR5+ model OCI-LY1 (day 114)
- Superior activity versus standard of care

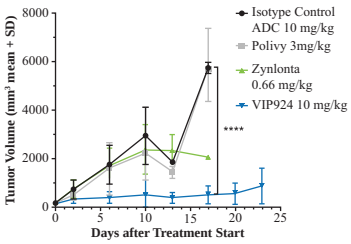
* P<0.05. **** P=0.0001 vs vehicle. #### P<0.0001 vs rituximab-bendamustine/ lenalidomide or CHOP. Tumor volumes on day 36. RR, response rate.

Additionally, evaluation in an MCL mouse model showed that VIP924 had superior efficacy and safety compared with Polivy® and Zynlonta® (FDA approved ADCs for B-cell lymphoma). In the study, we observed that animals treated with VIP924 exhibited significant inhibition of tumor growth and experienced a survival benefit compared with Zynlonta- and Polivy-treated animals. Additionally, Zynlonta-treated animals demonstrated reductions in white blood counts, monocytes, and lymphocytes at the end of the treatment, whereas VIP924 treatment showed minimal to no effects on these cell populations.

Survival of REC-1 transplanted humanized NSG mice under treatment



REC-1 in humanized NSG mice



**** On day 17, tumor volumes of VIP924 treated animals were significantly lower (P<0.00002) compared with control.

Potential Clinical Path

VIP924 can be evaluated in B-cell malignancies, such as MCL, FL, DLBCL, and CLL in monotherapy and in combination. Our goal is to progress VIP924 to an IND application in late 2025 or early 2026 once additional funding is secured.

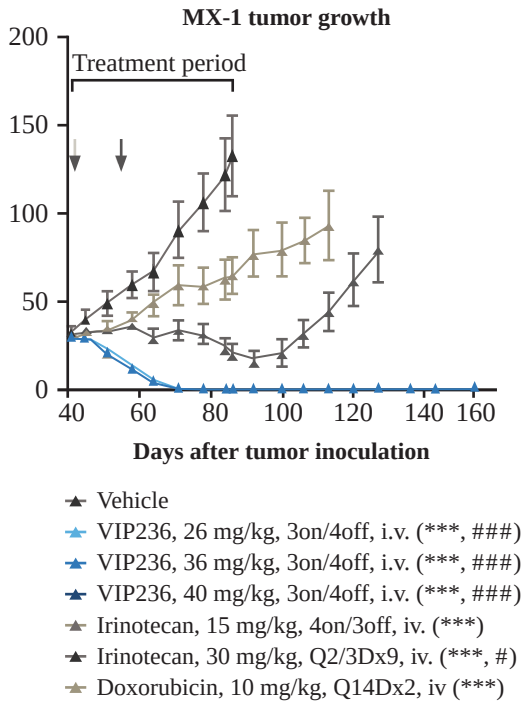
Small Molecule Drug Conjugate: VIP236

VIP236 is a first-in-class SMDC created with our VersAptx Platform. It consists of an $\alpha_v ß_3$ integrin binder, a neutrophil elastase linker cleaved in the TME, and an optimized CPT for high permeability and low efflux. Activated $\alpha_v ß_3$, an integrin found on tumor cells and in the TME, is overexpressed in advanced and metastatic tumors. $\alpha_v ß_3$ is a well-established target in solid tumors and, when used as a homing mechanism, allows for targeted delivery of our optimized CPT payload. We believe this approach enhances the efficacy of tumor treatment and the payload's safety profile.

Preclinical Results

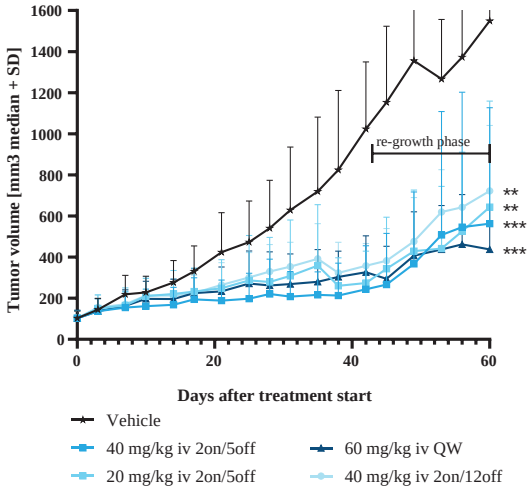
In numerous preclinical studies, we observed significant and superior tumor regression across various cell- and patient-derived xenograft models with VIP236 as compared with standard of care. In the TNBC MX-1 model below, we show that VIP236 has superior tumor regression compared with common chemotherapies, irinotecan and doxorubicin. In a liver metastasis from colorectal cancer model, we observed that VIP236 caused statistically significant tumor growth inhibition and delayed re-growth.

Triple Negative Breast Cancer



*** P < 0.001 compared with vehicle, # P < 0.05 compared with doxorubicin or cisplatin, ### P < 0.001 compared with doxorubicin or cisplatin or 5-FU.

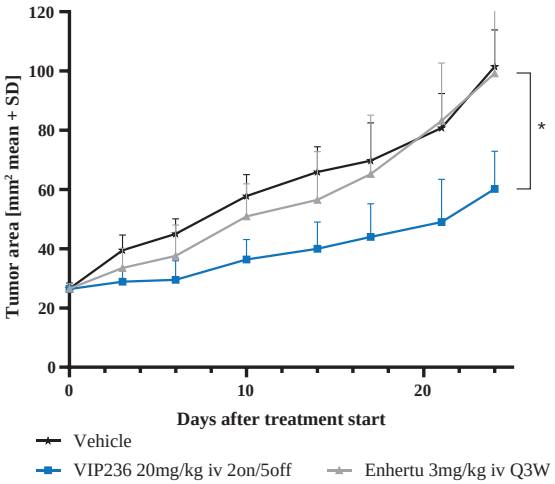
Liver Metastasis from Colorectal Cancer



* P < 0.05 compared with vehicle , ** P < 0.01 compared with vehicle, *** P < 0.001 compared with vehicle, **** P < 0.0001 compared with vehicle

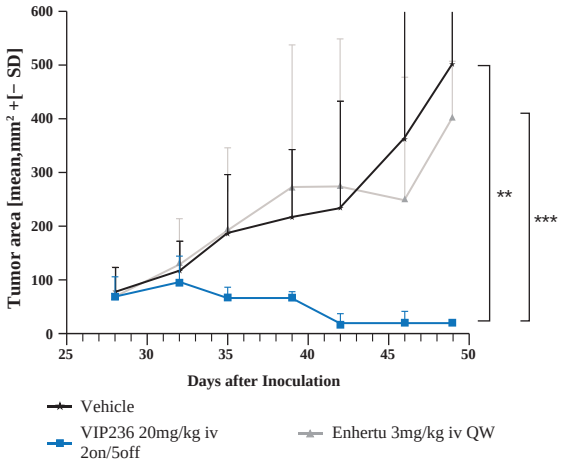
Most notably, preclinical data show enhanced efficacy in patient-and cell line-derived gastric cancer models in NMRI nude mice compared with ENHERTU® (an ADC approved specifically in HER2+gastric and gastroesophageal junction cancer). In these models, ENHERTU had very little effect on tumor growth, while VIP236 slowed and even caused tumor regression independent of HER2 expression.

NCIN87 HER2^{high}



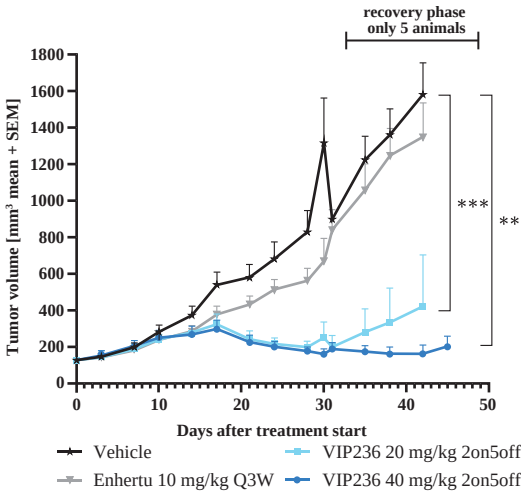
* P<0.05 vs vehicle.

SNU 16 HER2^{neg}



** P<0.01. *** P<0.001 vs vehicle.

GXA3040 HER2^{low}



** P<0.01. *** P<0.001 vs vehicle.

Clinical Studies

VIP236 is being evaluated in a Phase 1 dose-escalation study treating patients with advanced or metastatic solid tumors (NTC05371054).

In January 2023, we dosed the first patient in this study. To date, we have dosed 20 patients with VIP236. Five patients were dosed in three dose cohorts on the initial schedule of 2 days on/5 days off. Fifteen patients have been dosed in four dose cohorts on the once every three-week schedule. Dose escalation continues on the once every three-week schedule. The early safety profile of the once every three-week dosing schedule remains very encouraging, and VIP236 is showing signs of dose-dependent clinical activity (i.e., tumor shrinkage). We expect to release more details regarding the preliminary dose escalation study data during the 2024 AACR Annual Meeting in April 2024.

Potential Clinical Path

Given preclinical and clinical data, VIP236 shows promising clinical potential across several indications, including ovarian and endometrial cancers, gastric cancer, and metastatic disease (specifically in TNBC and lung cancer).

Enitociclib (P-TEFb/CDK9 inhibitor)

Enitociclib is a best-in-class and highly selective CDK9 inhibitor. Enitociclib effectively blocks P-TEFb-mediated activation of RNA polymerase II, preventing transcription of MCL1 and MYC, proteins associated with poor prognosis in various types of cancer. Enitociclib's mechanism of action is different from other CDK9 inhibitors, offering a more targeted approach, ultimately leading to cell death and reduction in tumor cell proliferation.

Preclinical Results

Preclinical studies support enitociclib as a best-in-class CDK9 inhibitor. The findings strongly suggest that enitociclib is highly selective and has a favorable safety profile, potentially making it an ideal combination partner in aggressive B-cell lymphomas and pediatric indications. Select preclinical studies are shown below:

In work performed in collaboration with the University of Calgary, enitociclib demonstrated potent cytotoxic activity as a single agent (IC50: 36-78 nM) and in combination with several anti-multiple myeloma (MM) agents in a small molecule inhibitor screening. In a JJN-3 MM xenograft mouse model, enitociclib monotherapy inhibited MYC and MCL1 transcription, inducing pro-caspase-3 and PARP cleavage within an hour of treatment, leading to reduction in tumor volumes by day 20 (96% to 99% tumor reduction). Further, enhanced efficacy was noted when enitociclib was combined with lenalidomide in a mouse model, confirming the earlier findings in the small molecule screening. Taken together, these preclinical results highlight the opportunity to advance enitociclib in optimization studies in MM.

In another University of Calgary collaboration, enitociclib was evaluated as a single agent and in combination in models of pediatric leukemia with KMT2A rearrangement, commonly seen in infant acute lymphoblastic leukemia and AML. Enitociclib alone achieved durable tumor inhibition and complete remission in a rat KMT2A leukemia model. In vitro, the combination of low dose enitociclib and various chemotherapies, prednisolone, and a KMT2A inhibitor showed significant synergistic cytotoxicity. These findings offer initial proof-of-concept for incorporating targeted cytotoxic agents with enitociclib in future clinical trials for KMT2A-rearranged leukemia, particularly in pediatric cases.

Clinical Studies

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

In this open-label Phase 1 study conducted by Bayer, enitociclib was assessed for safety, tolerability, and preliminary anti-tumor activity in patients with advanced hematologic malignancies. The study was concluded early, with 21 patients with relapsed/refractory AML treated. Enitociclib demonstrated a consistent safety profile across different dose levels, with gastrointestinal side effects and cytopenia being the most common adverse

events. Notably, no dose-limiting toxicities (DLTs) were reported. The study did not include patients with other hematologic malignancies (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, later taken-over by Vincerx and renamed VNC-152-101, designed to evaluate enitociclib as a monotherapy in patients with advanced cancer, including solid tumors and non-Hodgkin lymphoma. In total, the study enrolled 63 patients in the dose escalation and expansion cohorts (Bayer enrolled 37 patients [31 in dose escalation and 6 in the expansion cohort for DH-DLBCL] and Vincerx enrolled 26 patients). Enitociclib showed a favorable safety profile, dose-proportional pharmacokinetics, and on-target pharmacodynamic activity. Early clinical benefits across various indications include two patients with DH-DLBCL who experienced durable complete metabolic remissions, which persisted even after stopping treatment during the COVID pandemic. Additionally, one patient with transformed follicular lymphoma and 13 patients with solid tumors achieved stable disease as their best response to treatment.

Monotherapy Activity

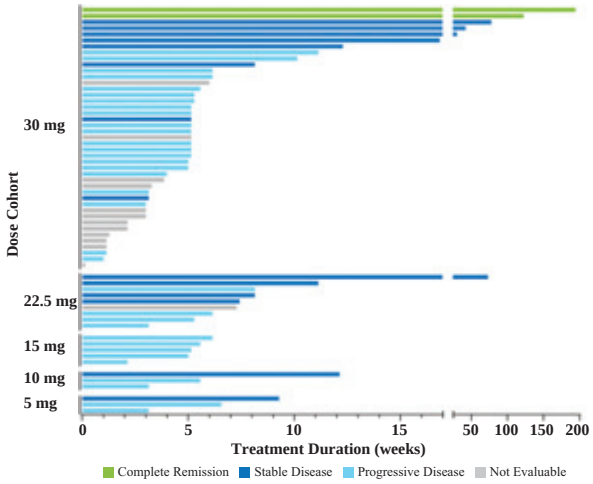
2 Complete Remissions (CR) of 7 DH-DLBCL (29% CR rate)

- 1 on treatment for 3.7 years
- 1 on treatment for 2.3 years
- Both patients continue in full remission ~2 years after stopping treatment

14 Patients had Stable Disease as Best Response

- 1 transformed follicular, 27 cycles*
- 5 ovarian cancer, 1 to 10 cycles
- 2 pancreatic cancer, 3 and 14 cycles
- 2 esophageal/nasopharyngeal, 2 and 3 cycles
- 1 salivary gland cancer, 24 cycles
- 1 breast cancer, 3 cycles
- 1 clival chordoma, 4 cycles
- 1 appendix cancer, 4 cycles

* ***As of January 2024.***



Study VNC-152-801: NIH Sponsored Study in R/R Lymphoid Malignancies

In April 2023, we began a study in partnership with the National Institutes of Health (NIH). This Phase 1 dose escalation study aims to establish the maximum tolerated dose and recommended Phase 2 dose and assess the safety and toxicity profile of the combination of enitociclib with venetoclax and prednisone (VVIP) in patients with relapsed/refractory lymphoid malignancies. As of January 2024, a total of 5 patients have been dosed in this study. Of these 5 patients, 2 out of 3 peripheral T-cell lymphoma (PTCL) patients (67%) achieved a partial response (PR) as a best response, with tumor regressions of 91% and 86%. Additionally, 1 DH-DLBCL patient out of 2 lymphoma patients achieved a PR (71% tumor regression) after just one treatment cycle, emphasizing the faster response rate of this combination compared with enitociclib monotherapy. There were no observed DLTs. Enrollment for this study continues.

Potential Clinical Path

We believe enitociclib's favorable safety profile makes it an ideal combination partner across numerous hematologic malignancies such as DLBCL and PTCL as well as MYC-driven solid tumors such as ovarian cancer. Further research in these areas will proceed once additional funding is secured.

Sales and Marketing

Because we are a clinical-stage company, we do not currently have our own marketing, sales, or distribution capabilities. To commercialize any of our product candidates, 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 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 to develop companion diagnostics to accompany our drug products. We 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 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 sector, 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. 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, bioconjugates, 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.

Although we believe our bioconjugation product candidates and VersAptx platform are highly differentiated, many companies continue to invest in innovation in the bioconjugate field, including new payload classes, new conjugation approaches, and new targeting moieties. Additionally, many companies have products and/or platforms that target the same indications our programs target. Any of these initiatives could lead to products that have superior properties to our VersAptx platform and bioconjugation product candidates. Some of

the companies that may compete with us include, AbbVie Inc., ADC Therapeutics SA, Astellas Pharma Inc., Astra-Zeneca PLC, Bicycle Therapeutics plc, Bristol-Myers Squibb Company, CytomX Therapeutics, Inc., Daiichi Sankyo Company, Limited, Duality Biologics Co. Ltd., Eli Lilly and Company, Genentech, Inc., Gilead Sciences, Inc., GSK plc, Iksuda Therapeutics Ltd, Innovent Biologics, Inc., ImmunoGen, Inc. (acquired by AbbVie, Inc.), Immunomedics, Inc., Johnson & Johnson Inc, Klus Pharma, Inc, LegoChem Biosciences, Inc., MacroGenics, Inc., Merck & Co., Inc, Mersana Therapeutics Inc., Novartis International AG, ProfoundBio Inc, Pyxis (which acquired Pfizer, Inc.'s ADC technology), Roche Holding AG, Sanofi S.A., Seagen, Inc. (acquired by Pfizer, Inc.), and Takeda Pharmaceutical Company Limited.

Although we also believe enitociclib is a best-in-class and highly selective CDK9 inhibitor that is highly differentiated from other CDK9 programs and therapies targeting the same indications, there are other CDK9 programs in development demonstrating clinical efficacy and several are further along in development than our programs. The companies with clinical-stage programs include Cyclacel Pharmaceuticals Inc., Kronos Bio, Inc., Merck & Co., Inc., Prelude Therapeutics Inc., SELLAS Life Sciences Group, Inc, and Sumitomo Dainippon Pharma Co., Ltd. These or other 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 P-TEFb 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.

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.

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, efficacy, 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, 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 FDA's current Good Laboratory Practices (GLP) requirements;
- submission to the FDA of an IND, which must be reviewed by the FDA before clinical trials may begin;
- approval by an independent Institutional Review Board or ethics committee for each clinical protocol before clinical trials may begin at each clinical trial site;
- performance of adequate and well-controlled human clinical trials in accordance with 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 clinical trial to resolve such concerns.

Clinical trials are studies that involve the administration of an investigational drug 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 informed consent for their participation. 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 drug 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 based on access to certain data from that clinical trial and may recommend a discontinuation 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 drug 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 of efficacy. For certain investigational drug products targeting 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 drug 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 drug 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.

During the development of a drug 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 data gathered to date, for the FDA to provide advice, and for sponsor and the FDA to reach agreement on the next phase of development.

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 drug 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 drug 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 and the FDA has approximately two months to make a "filing" decision after submission.

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 drug product candidate and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response Letter (CRL). An approval letter authorizes commercial marketing of the drug product with specific prescribing information for specific indications. A CRL would describe all deficiencies that FDA has identified in the NDA/BLA, except that where FDA determines that the data supporting the application are inadequate to support approval, it may issue the CRL without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the CRL, 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 drug product may be marketed. For example, the FDA may approve an 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 developed to manage a known or potential serious risk associated with a drug 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 this 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 drug product candidate submitted to the FDA for approval may be eligible for programs intended to expedite 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 drug 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 drug 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 drug 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 would 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 safety and efficacy.

Different pricing and reimbursement schemes exist in other countries. For example, 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 countries may require the completion of clinical studies that compare the cost effectiveness of a particular product candidate to currently available therapies. Others 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 companion diagnostic, then the FDA generally will require approval or clearance of that diagnostic at the same time that it 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 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 efficacy 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, 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 such clinical trials are conducted and 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, 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. Premarket approval can include post-approval conditions that the FDA believes necessary to ensure the safety and efficacy 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. This 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. We believe that our suppliers are in material compliance with applicable environmental health and safety laws and that continued compliance will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect their or our future operations.

Other Regulations

We may also be 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 drug 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 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 VIP236, VIP943, VIP924, enitociclib, VIP217, and our other current drug product candidates and technologies from Bayer on an exclusive, worldwide basis under the Bayer License Agreement. The in-licensed portfolio as of December 31, 2023 includes 34 issued U.S. patents, 9 pending U.S. patent applications, 293 issued patents in various jurisdictions outside of the United States and approximately 84 pending patent applications in various jurisdictions outside of the United States. The Bayer License Agreement is described more fully below.

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. With respect to VIP943 and VIP924, we have pending applications in the U.S., Europe, China, Japan, India, Argentina, Brazil, and Mexico, along with issued patents and pending applications in other markets covering the composition of matter and uses of VIP943 and VIP924. Any patent that may issue from our pending patent applications related to VIP943 and VIP924 are expected to expire by July 2044, absent any patent term adjustments or extensions. 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.

As of December 31, 2023, we own 28 pending patent applications, including five pending U.S. provisional applications, nine Patent Cooperation Treaty (PCT) applications, and 14 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 versatile and adaptable bioconjugation platform, now referred to as the VersAptx Platform, including VIP943 and VIP924, next-generation ADCs, and VIP236, an SMDC, and (ii) a small molecule drug program, including enitociclib, a P-TEFb/CDK9 inhibitor. The VersAptx Platform and these product candidates, currently comprise our entire product 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, 2023, we had 42 full-time employees globally, 62% of whom hold a Masters' degree or higher and 33% of whom hold an M.D. or Ph.D. Of our 42 employees, 64% were engaged in research and development and 36% were engaged in general and administrative functions. Of our total number of employees, 19% are based outside of the United States in one of three other countries. The median age of our staff was 44, and 69% 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 addition, we offer a benefit called Summer Hours from Memorial Day through Labor Day, during which we shorten each Friday to half-working days but continue to pay employees their full day's salary. We also offer learning and development opportunities for our employees, such as 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 engagement surveys in 2023 showed 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 2023, 52% of our employees worked half-time remote and 40% worked full-time remote, rather than from one of our two global offices located in Palo Alto, California, and Monheim, Germany. Only 7% of our employees were office-based. 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, 38% of our U.S. employees reported they were born outside of the U.S., and 47% of our U.S. employees speak a native language other than English. Women make up 45% 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. Of our U.S. employees, 65% reported they have caring responsibilities outside of work, 12% identify as LGBTQ+, 6% 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. We may from time to time become involved in legal proceedings arising in the ordinary course of business.

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 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 VIP236, VIP943, VIP924, enitociclib, the VersAptx Platform, and other product candidates and technologies that incorporate such intellectual property, raise capital, or continue our operations.

We have licensed our current core patents and other intellectual property relating to VIP236, VIP943, VIP924, enitociclib, the VersAptx Platform, 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 prospects and our ability to develop and commercialize our current product candidates, raise capital, or continue our operations.

We are substantially dependent on the success of VIP236, VIP943, and enitociclib, 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 VIP236, VIP943, and enitociclib, 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 our 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 and prospects.

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.

VIP236, VIP943, and VIP924 are the first product candidates from our VersAptx Platform, the potential therapeutic benefits of which are unproven, and we may never develop, successfully conduct, or complete clinical trials, obtain marketing approval, and commercialize these or any other product candidates from our VersAptx 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 suggests, 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 VIP236, VIP943, and VIP924 have shown proof-of-concept for each, these product candidates 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 VIP236, VIP943, and VIP924 in pivotal clinical trials or in obtaining marketing approval thereafter.

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. In addition, enitociclib may not demonstrate in patients any or all of the pharmacological benefits we believe it may possess. Positive results from preclinical studies or early stage clinical trials are not necessarily predictive of the results of planned clinical trials of enitociclib. 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.

If we are unable to successfully develop, conduct, or complete clinical trials, obtain marketing approval, and commercialize our product candidates, our business and prospects would be materially harmed.

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.

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 subsequent or 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 and prospects.

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 and new therapies 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, in clinical trials, or in development that are, or 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.

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 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 pharmacodynamic 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 therefore 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. 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 prospects.

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 in the future be, adversely affected by the effects of health pandemics and epidemics.

Our business has been, and could in the future be, adversely affected by health pandemics and epidemics 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. 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. Disruptions in operations, whether related to COVID-19 or other health pandemics or epidemics, have impacted, and could in the future 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. If our relationships with our suppliers or other vendors are delayed, scaled back, or terminated as a result of health pandemics or epidemics 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.

In addition, our clinical trials have been, and could in the future be, affected by health pandemics or epidemics. Clinical site initiation and patient enrollment have been, and could in the future 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.

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, which could negatively impact our ability to conduct clinical trials and have an adverse effect on our business and financial condition.

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

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.

Dr. Ahmed M. Hamdy and Dr. Raquel E. Izumi were the principal co-founders of Acerta Pharma BV, the company that developed CALQUENCE® and was eventually acquired by AstraZeneca plc. 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.

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

Our business is highly dependent on our ability to attract and retain management, clinical development, scientific, research, 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 and prospects. 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, wars (such as the wars in Ukraine and Israel), 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 third parties upon whom we rely, or conduct our preclinical studies or clinical trials, may have a material adverse effect on our business. In addition, 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 facilities of the third parties on whom we rely, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, our business 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, or 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. 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 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, proceedings against us 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 December 2018, 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 expect to continue to incur significant net losses for the foreseeable future, and there can be no assurance we will be able to raise capital.

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, manufacturing, 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 and may not be able to continue as a going concern.

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, VIP236, VIP943, VIP924, enitociclib, 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 expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to maintain our continuing operations.

As of December 31, 2023, we had approximately $12.8 million in cash and cash equivalents. 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 our current business plans and assumptions, we believe that our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements into July 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 inflation and other economic and market conditions, the wars in Ukraine and Israel, the inability to maintain our listing on The Nasdaq Capital Market, 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, or curtail our operations.

In accordance with Accounting Standards Update ("ASU") 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern* (Subtopic 205-40), we have evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern for a period of one year after the date that our audited consolidated financial statements are issued. In light of our existing cash resources and current and expected operating losses and negative cash flows, we expect to need additional capital prior to the one-year anniversary of the issuance of our audited consolidated financial statements, and such additional capital may not be available as and when needed on acceptable terms or at all. As a result, we have concluded that these circumstances and the uncertainties associated with our ability to obtain additional capital raise substantial doubt about our ability to continue as a going concern for a period of one year after the date that our audited consolidated financial statements are issued.

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, and we may not be able to raise additional capital or enter into strategic alliances at levels sufficient to pay these amounts when due.

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. Accordingly, we will need to obtain substantial additional funding or enter into strategic alliances in order to make these payments, and 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 amounts or at all. If we are unable to pay these amounts, 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 or sustain 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. Even if we achieve profitability, we may not be able to sustain profitability in subsequent periods.

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 and optimization, efficacy, approval, recordkeeping, reporting, labeling, storage, packaging, advertising, and 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 all required 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 has transformed the dose-finding and dose optimization paradigm across oncology to emphasize selection of a dose or doses that maximizes not only efficacy of a drug but its safety and tolerability as well, which could increase the development time and costs of our clinical trials. In addition, the European Union has transitioned to full implementation of the EU Clinical Trials Regulation in January 2022, and the United Kingdom's Medicines and Healthcare products Regulatory Agency transitioned the United Kingdom to a fully independent clinical trial regulatory framework, 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 such product candidate or the labeling or other restrictions of such product candidate. 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 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 previously observed. 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 such product candidates are used in combination with other therapies, they may exacerbate adverse events associated with the other 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 such 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 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 such 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. A failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the 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 would 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 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 those product candidates, may contain significant limitations related to use restrictions, warnings, precautions, or contraindications, and may include burdensome post-approval studies 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, reports, and registration, as well as 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 processes;
- warning or untitled letters;
- civil and criminal penalties;
- injunctions;
- suspension or withdrawal of regulatory approvals;
- seizures, detentions, or import bans;
- voluntary or mandatory 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, generate negative publicity, and harm our business and prospects.

There can be no assurance that we will be able to pursue accelerated or other expedited approval of any of our product candidates, and the failure to obtain such accelerated or other expedited approval would result in a longer time period to commercialization of such product candidates, which could increase the cost of development and harm our competitive position in the marketplace.

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 expedited 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 such 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.

There can be no assurance that we will decide to pursue, or subsequent to FDA feedback continue to pursue, accelerated approval or any other form of expedited development, review, or approval. Furthermore, even 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 would be accepted or that any expedited development, review, or approval would 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.

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 cannot guarantee that we will always be 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. 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, and our corporate compliance programs cannot guarantee that we will always be in compliance with all relevant laws and regulations. Violations are punishable by significant criminal and civil fines and other penalties, as well as the possibility of exclusion of the affected 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 and prospects.

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

We cannot ensure that our corporate compliance controls, policies, and procedures will in every instance protect us from acts committed by our employees, agents, contractors, or collaborators, including contract research organizations, electronic data capture companies, data management companies, contract clinical

research associates, medical institutions, clinical investigators, contract laboratories, and other third parties, that would violate the laws or regulations of the jurisdictions in which we operate, including healthcare, employment, foreign corrupt practices, environmental, competition, and privacy laws and regulations. Such improper actions could subject us to civil or criminal investigations, and civil penalties, and could adversely impact our business and prospects.

For example, we are subject to the Foreign Corrupt Practices Act and similar anti-bribery or anti-corruption laws, regulations, and 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, and our dealings with these prescribers and purchasers are therefore 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 such laws and regulations could result in, among other things, administrative, civil and criminal fines and sanctions against us, our directors, officers, or employees, the closing 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 and prospects.

Risks Related to Our Dependence on Third Parties

Our manufacturing processes are complex, and we do not currently have our own manufacturing capabilities 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 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 manufacturers. 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. Certain of our key third-party manufacturers are located in China, and the United States and China are currently experiencing geopolitical tensions that could result in legislation or government intervention that adversely impacts our ability to manufacture in China, which could necessitate transitioning such manufacturing to other third-party manufacturers and increase costs, delay manufacturing, and lengthen timelines. In addition, the European Union,

which is experiencing, and could continue to experience, the impact of the wars in Ukraine and Israel on supply chains, and other economic matters, including inflation. Such third-party manufacturers may implement, and certain of such manufacturers have implemented, price increases that could negatively impact our ability to afford their services.

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 may 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 improvements.

Any inability to identify and retain third-party manufacturers on a cost-effective basis, any performance failure on the part of such manufacturers, or any disruption in our supply chain as a result of economic uncertainty, political unrest, the wars in Ukraine and Israel, trade disputes, natural disasters, pandemics or epidemics, climate change, or otherwise, could delay the development, clinical trials, regulatory approval, or commercialization of our product candidates, which would harm our business and prospects.

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 such 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, require us to relinquish important rights, limit our commercial opportunities, or otherwise be on terms unfavorable to us.

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

- we may not be able to control the amount and timing of resources that our collaborators may devote to our 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 its 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 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.

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 certain extent upon previous development conducted by Bayer or other third parties over whom we had no control and before we in-licensed such 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 such 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 conduct clinical trials, which could delay, limit, or prevent regulatory approval for our product candidates.

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 such 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 or 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 VIP236, VIP943, VIP924, enitociclib, 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 and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product 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 intellectual property for VIP236, VIP943, VIP924, enitociclib, 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, 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 business and prospects.

Although we have licensed issued patents that cover certain of our product candidates and technologies, we do not have issued patents covering all our product candidates and technologies, and we may need additional issued patents covering such product candidates and technologies. We cannot be certain that the claims in any of our U.S. pending patent applications, corresponding international patent applications, 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 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 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.

In addition, 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.

Furthermore, our ability to obtain and maintain valid and enforceable patents also 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 after filing, we may not be certain that we or our licensors are the first to file any patent application related to our drug product candidates or technologies, potentially having a material adverse effect on our business and prospects. This will require us to be to be aware of the possibility of adverse determinations in any such submissions or proceedings, potentially reducing the scope or enforceability of, or invalidate, our patent rights, which would adversely affect our competitive position.

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 in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our product candidates. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. In addition, if the breadth or strength of protection provided by our patents and patent applications or the patents and patent applications of our licensors is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop, or commercialize current or future product candidates.

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.

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 current or future product candidates, technologies, or VersAptx platform. 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 current or future product candidates, technologies, or VersAptx platform. 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 products and practicing our own patented technologies.

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 relevant inventions or to attempt to license rights from the prevailing party. Our business could be harmed if the prevailing party would 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 clinical trials or 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.

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 or other proceedings may be necessary to defend against these and other claims challenging inventorship or ownership. For example, 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. 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 and prospects. 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 not 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. 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 products of third parties. 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. This Act permits a patent restoration term of up to five years as compensation for patent term lost during product development and FDA regulatory review. A maximum of one patent may be extended per FDA approved product as compensation for the patent term lost during FDA regulatory review. 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 to 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 can 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 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.

The requirements for patentability differ regionally. Some countries limit the enforceability of patents against government agencies or government contractors, while others have compulsory licensing laws under

which a patent owner may be compelled to grant licenses to third parties. 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 and prospects may be adversely affected.

The standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. As such, we do not know the degree of future protection that we will have on our technologies and product candidates. While we will endeavor protect our technologies and product candidates with intellectual property rights such as patents, the process of obtaining patents is time consuming, expensive, and unpredictable. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of some countries do not favor patent enforcement and other intellectual property protection, which could make it difficult for us to stop infringement of our patents or our licensors' patents or marketing of competing products in violation of our proprietary rights.

Beginning in March 2023, European patent applicants have the option of participating in the Unitary Patent System ("UPS"), subject to the jurisdiction of the Unitary Patent Court ("UPC"), on an issued patent-by-issued patent, or patent application-by-patent application basis. This new system is a significant change in European patent practice, and the UPC is a new court system, with no established legal precedent, resulting in uncertainty for patent holders and applicants. We will consider, case-by-case, with each individual patent or application, the risks and benefits of participating in the UPS. We will continue to monitor the evolution of the UPS and UPC, especially over the course of its seven-years' transitional period as the new system and the new court gains footing.

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.

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 many 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 relevant 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 and prospects.

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 and technologies. 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 business 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 and prospects could be adversely affected.

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

We rely on the protection of our proprietary information, including our technologies and know-how, to maintain our competitive position. Although we have taken steps to protect such information, including entering confidentiality agreements with third parties and confidential information and inventions agreements with employees, consultants, and advisors, we cannot provide any assurances that these parties would not breach such agreements and disclose our proprietary information, and we may not be able to obtain adequate remedies in the event of such breaches. Enforcing claims that a party illegally used or disclosed such information is difficult, expensive, and time-consuming, and the outcome is unpredictable. Moreover, third parties may obtain or come upon this or similar information independently, and we would have no right to prevent them from using that information to compete with us. If any of these events occurs or if we otherwise lose such protection, the value of our proprietary information may be greatly reduced, and our competitive position would be harmed.

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 of third parties.

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 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 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 in discovery, and adversely impact our ability to market or otherwise commercialize our product candidates and technologies. 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 such claims, such 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 on commercially reasonable terms or at all.

Third parties 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 such 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 intellectual property rights. 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 current or future product candidates, which could impair our competitive position. There is a substantial amount of litigation and administrative proceedings, 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. 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 pharmaceutical 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, 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 prior art that we do not believe is relevant to our business may, ultimately, be found to limit our ability to make, use, sell, offer for sale, or import our current or future products and 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 large 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 and prospects.

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 technologies 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 third-party proprietary rights. We may be unable to acquire or in-license any compositions of matter, methods of use, processes, or other third-party intellectual property rights that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is competitive, 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 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 and prospects.

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 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 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 and prospects.

Risks Related to Operating as a Public Company

If we are not able to maintain compliance with the continued listing requirements of The Nasdaq Capital Market, our common stock may be delisted, which could negatively impact the liquidity and price of our common stock, our ability to access the capital markets, and the confidence of investors and others.

On September 14, 2023, we received written notice from The Nasdaq Stock Market LLC ("Nasdaq") that the closing bid price of our common stock for the prior 30 consecutive business days was lower than the minimum bid price requirement of $1.00 per share. On January 12, 2024, we received written notice from Nasdaq that we had regained compliance with the minimum bid price requirement. However, there can be no assurance that we will be able to continue to maintain compliance with the Nasdaq continued listing requirements, and if we fail to do so and Nasdaq delists our common stock, we could face material adverse consequences, including:

- limited availability of market quotations and decreased liquidity for our common stock, resulting in a decline in the trading price of our common stock;
- adverse impact on the ability of stockholders to sell our common stock;
- limited news and analyst coverage and negative publicity; and
- decreased ability to raise capital and potential loss of confidence by investors, suppliers, customers, collaborators, and employees.

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, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, the Public Company Accounting Oversight Board, the securities exchanges, and the rules and regulations thereunder 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 us and also increase our costs of obtaining 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 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.

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 have in the past and may in the future determine that there are material weaknesses in our internal control over financial reporting. Any 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 and prospects.

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 the completion of the Business Combination, our common stock has been 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 levels, capital requirements and capital raising activities, including issuances of securities or the incurrence of debt;
- our ability to enter into and maintain collaboration arrangements;
- 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 biotechnology companies have experienced significant stock price declines and 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 and prospects.

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 December 31, 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 otherwise converted into shares of our common stock 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. Sales, or potential sales, of substantial numbers of shares in the public market could increase the volatility of, or adversely affect, the market price of our common stock.

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 our 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 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 and prospects.

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

As of December 31, 2023, Dr. Ahmed M. Hamdy, our Chief Executive Officer, and Dr. Raquel E. Izumi, our President and Chief Operations Officer, together beneficially owned, directly or indirectly, approximately 17.7% of our outstanding common stock, and our directors and executive officers as a group beneficially owned approximately 23.3% 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.

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.

ITEM 1B. Unresolved Staff Comments.

None.

ITEM 1C. Cybersecurity.

Risk Management and Strategy

We have developed and implemented a cybersecurity policy for assessing, identifying, and managing material risks from cybersecurity threats and have integrated this policy into our overall risk management framework and policies. This policy applies to all of our employees, contractors, and consultants, and any other users who have permanent or temporary access to our data and systems, regardless of their location, device, or network, and all of our employees, contractors, consultants and other users are expected to read, understand, and adhere to this policy and its associated processes and procedures.

Our cybersecurity policy also encompasses the risks associated with our use of third-party service providers. We conduct assessments of our third-party service providers before engagement and maintain ongoing monitoring intended to ensure compliance with our cybersecurity standards.

We are subject to various cybersecurity risks that could adversely affect our business, financial condition, and results of operations, including intellectual property theft; fraud; extortion; harm to employees, customers, or

patients; violation of privacy laws; and litigation, legal, and reputational risk. We have implemented an approach to identify and assess the threats and vulnerabilities that could affect our data and systems. Our policy is aligned with industry standards and best practices, such as the National Institute of Standards and Technology's ("NIST") Cybersecurity Framework Standard (800-53 -Security and Privacy Controls for information Systems and Organizations).

Supporting technologies, processes, and procedures under our cybersecurity policy include the following:

- identification, credential/authentication, and access management for all users prior to accessing any data and systems;
- encryption of all data at rest and in transit for all devices and cloud services;
- firewalls, antivirus software, security traffic inspections, and other endpoint protection and monitoring tools and techniques;
- automatic updates and patches of all software and systems regularly and fix of all known or reported bugs or vulnerabilities promptly;
- data loss prevention through regular backup of all data and systems and storage of backups in secure and separate locations;
- cybersecurity awareness training for all users to educate them on our policy and procedures as well as best practices, potential vulnerabilities, and common threats and promote a culture of cybersecurity risk management;
- cybersecurity incident response plans that include procedures for analyzing, reporting, and responding to cybersecurity incidents; and
- third-party risk management procedures for service providers, suppliers, and vendors.

We maintain a security team to continuously monitor our data and technology infrastructure, report and respond to cybersecurity incidents, work with users, and report to management and the audit committee. We also maintain a cybersecurity risk insurance policy.

We have not encountered any cybersecurity incidents that have materially affected our business, results of operations, or financial condition.

Governance

Our board of directors considers cybersecurity risk as part of its overall risk oversight function and has delegated that oversight role to the audit committee. The audit committee oversees the implementation of our cybersecurity risk management under the cybersecurity policy.

The audit committee receives regular reports from management on our cybersecurity risks, controls, tools, and incidents. The audit committee reports to the full board of directors regarding its activities, including those related to cybersecurity.

Our Senior Director, IT, Document & Training Compliance, has primary responsibility for developing and implementing our cybersecurity policy and procedures and assessing, monitoring, and managing the prevention, detection, mitigation, and remediation of our cybersecurity risks and incidents. He has served in various roles in information technology and information security for over 20 years, and the IT team holds multiple industry-recognized certifications.

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 26, 2024, there were 10 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 have 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 versatile and adaptable bioconjugation platform, now referred to as the VersAptx Platform, including next-generation ADCs VIP943, in Phase 1 trials, and VIP924, in preclinical studies, and VIP236, an SMDC, on Phase 1 trials, and (ii) a small molecule drug program, including enitociclib, a P-TEFb/CDK9 inhibitor in an NIH-sponsored Phase 1 trial. We intend to use these product candidates to treat various cancers in a patient-specific, targeted approach and believe 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 U.S. 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 track our research and development expenses on a program-by-program basis as such costs are deployed across multiple programs 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 anticipate that our research and development expenses will increase in the future as we continue to 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 studies required to advance our product candidates into clinical trials, including the impact of factors such as inflation, the wars in Ukraine and Israel, supply chain disruptions, and health pandemics and epidemics;
- per patient clinical trial costs, including based on the number of doses that patients receive and the cost of drug products for combination therapies;
- 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;
- the availability of capital;
- 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 expand our operations and infrastructure to support the initiation, continuation, and expansion of our preclinical 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, 2023 and 2022

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

	For the years ended December 31,		
	2023	2022	Amount Change
Operating expenses:			
General and administrative	$ 13,636	$ 18,885	$ (5,249)
Research and development	28,973	49,837	(20,864)
Restructuring	—	2,469	(2,469)
Total operating expenses	42,609	71,191	(28,582)
Loss from operations	(42,609)	(71,191)	28,582
Other income (expense)			
Change in fair value of warrant liabilities	(47)	6,303	(6,350)
Interest income	1,251	664	587
Other income (expense)	1,248	1,240	8
Total other income (expense)	2,452	8,207	(5,755)
Net loss	**$(40,157)**	**$(62,984)**	**$ 22,827**

Research and Development

Research and development expenses decreased by $20.9 million for the year ended December 31, 2023 compared to the year ended December 31, 2022. This decrease primarily relates to decreases in third party service and supplier expenses, including manufacturing services associated with our ADC program of approximately $9.7 million and clinical services of approximately $2.6 million, as well as decreases in expenses related to headcount, including declines in stock-based compensation of approximately $3.3 million and employee salaries of approximately $3.1 million as a result of our headcount reduction in June 2022.

General and Administrative

General and administrative expenses decreased by approximately $5.2 million for the year ended December 31, 2023 compared to the year ended December 31, 2022 primarily as a result of decreases in stock-based compensation expense of $2.8 million, professional services of $1.4 million, and a decrease in expenses related to headcount of $0.7 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 our 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 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, 2023 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, resulting in a $6.3 million gain in 2022. The closing stock price increased from $1.02 at December 31, 2022 to $1.18 at December 31, 2023, resulting in an immaterial change of approximately $50,000 to the fair value of our warrants.

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 from $0.7 million for the year ended December 31, 2022 to $1.3 million for the year ended December 31, 2023 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 $1.0 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, 2022 to the year ended December 31, 2023 by $37.7 million (to $9.1 million from $46.8 million) primarily as a result of cash used in operations of $40.5 million in fiscal 2023. 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 operating expenses in 2024 to be comparable to 2023, subject to raising additional capital. We intend to prioritize resources towards advancing Phase I studies in these two lead programs and control spending, including discretionary spending, in other areas. We believe we can adjust our operating plan spending levels based on the timing of future clinical trials, which are predicated upon adequate funding to complete the trials. We routinely evaluate the status of our clinical development programs as well as potential strategic options. 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. In addition,

we are 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. As of December 31, 2022, the Company recorded a $1.0 million development milestone payable to Bayer, which was subsequently paid, in connection with our IND filing for VIP236. As of December 31, 2023, we paid another $1.0 million development milestone to Bayer in connection with our IND filing for VIP943. The size and timing of future 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, 2023, we had approximately $12.8 million in cash and cash equivalents. 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. 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 early third quarter 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.

The failure to raise additional capital as and when needed or on acceptable terms would have a negative impact on our financial condition and the ability to pursue our business strategy, and we may have to reduce our workforce or delay, reduce the scope of, suspend, or eliminate one or more preclinical programs, clinical trials, or future commercialization efforts, or curtail our business operations. In light of our existing cash resources and current and expected operating losses and negative cash flows, we will need additional capital prior to the one-year anniversary of the issuance of our audited consolidated financial statements, and such additional capital may not be available as and when needed on acceptable terms or at all. As a result, we have concluded that these circumstances and the uncertainties associated with our ability to obtain additional capital raise substantial doubt about our ability to continue as a going concern for a period of one year after the date that our consolidated financial statements are issued.

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 revenue, 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 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 wars in Ukraine and Israel. 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 audited consolidated financial statements included elsewhere in this report), we have consolidated our leased office space at our corporate headquarters location. Effective July 2022, we subleased substantially all of our unused office space for a term of 18 months at a base rent of $50,000 per month. Such payments received in the years ended December 31, 2023 and December 31, 2022 were $0.6 million and $0.3 million, respectively. In January 2024, the sublease was extended to include additional space for an additional 24 months at a base rent of approximately $50,000 per month.

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,	
	2023	2022
Net cash used in operating activities	$(40,453)	$(59,604)
Net cash provided by (used in) investing activities	$ 41,500	$(40,578)
Net cash provided by financing activities	$ 114	$ 280

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 to expand clinical trials of, and seek marketing approval for, our product candidates, we expect our cash used in operating activities to increase over time before we start to generate any material cash flows from our business.

Net cash used in operating activities was approximately $40.5 million for the year ended December 31, 2023 compared to $59.6 million for the year ended December 31, 2022. 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, 2023 was approximately $40.2 million, which included approximately $3.6 million related to stock-based compensation.

Cash Flows from Investing Activities

Cash provided by investing activities was $41.5 million for the year ended December 31, 2023, consisting of sales and maturities of marketable securities of approximately $53.3 million used to fund our operating activities, offset by purchases of approximately $11.8 million. 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 Flows from Financing Activities

Net cash provided by financing activities was $0.1 million and $0.3 million for the years ended December 31, 2023 and December 31, 2022, respectively, consisting of proceeds received from the issuance of common stock under our employee stock plans.

Off-Balance Sheet Arrangements

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

Critical Accounting 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 consolidated financial statements included elsewhere in this report. The critical accounting estimates 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 filings of each of our IND for VIP236 in December 2022 and our IND for VIP943 in August 2023, we have paid $1.0 million development milestone payments 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, 2023, 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 the 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 were 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, 2023 and December 31, 2022. See Note 6 to the audited consolidated financial statements in this report.

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, 2023, we possess cash equivalents. 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.

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the 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, 2023 and 2022, 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, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the entity will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the entity has incurred recurring losses from operations and expects to continue to incur operating losses that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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, audits 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.

East Brunswick, New Jersey

March 29, 2024

PCAOB ID Number 100

Vincerx Pharma, Inc.
Consolidated Balance Sheets

(In thousands, except share and per share amounts)

	December 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 12,782	$ 11,663
Restricted cash	72	70
Short-term marketable securities	—	40,796
Prepaid expenses	51	134
Grant receivable	1,044	1,372
Other current assets	784	1,929
Total current assets	14,733	55,964
Right-of-use assets, net	2,201	3,064
Property, plant and equipment, net	125	177
Other assets	1,158	81
Total assets	**$ 18,217**	**$ 59,286**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 2,497	$ 4,065
Accrued expenses	1,755	3,923
Lease liability	1,162	1,024
Common stock warrant liabilities	191	144
Total current liabilities	5,605	9,156
Lease liability, net of current portion	1,340	2,412
Other noncurrent liabilities	50	50
Total liabilities	6,995	11,618
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, 2023 and 2022	—	—
Common stock, $0.0001 par value; 120,000,000 shares authorized; 21,407,510 shares and 21,242,884 shares issued and outstanding as of December 31, 2023 and 2022, respectively	2	2
Additional paid-in capital	170,324	166,647
Accumulated other comprehensive income (loss)	8	(26)
Accumulated deficit	(159,112)	(118,955)
Total stockholders' equity	11,222	47,668
Total liabilities and stockholders' equity	**$ 18,217**	**$ 59,286**

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,	
	2023	**2022**
Operating expenses:		
General and administrative	$ 13,636	$ 18,885
Research and development	28,973	49,837
Restructuring	—	2,469
Total operating expenses	42,609	71,191
Loss from operations	(42,609)	(71,191)
Other income (expense)		
Change in fair value of warrant liabilities	(47)	6,303
Interest income	1,251	664
Other income (expense), net	1,248	1,240
Total other income (expense)	2,452	8,207
Net loss	**$(40,157)**	**$(62,984)**
Other comprehensive income (loss):		
Net foreign currency translation gain (loss)	(40)	69
Net unrealized gain (loss) on marketable securities	74	(74)
Comprehensive loss	**$(40,123)**	**$(62,989)**
Net loss per common share, basic and diluted	$ (1.89)	$ (3.00)
Weighted average common shares outstanding, basic and diluted	21,295	21,029

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

Vincerx Pharma, Inc.
Consolidated Statements of Changes in Stockholders' Equity
For the years ended December 31, 2023 and 2022

(In thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of January 1, 2022	**21,057**	**$ 2**	**$156,311**	**$ (21)**	**$ (55,971)**	**$100,321**
Issuance of common stock from employee stock plans	186	—	280	—	—	280
Stock-based compensation	—	—	10,056	—	—	10,056
Cumulative translation adjustment	—	—	—	69	—	69
Unrealized loss on marketable securities	—	—	—	(74)	—	(74)
Net loss	—	—	—	—	(62,984)	(62,984)
Balance as of December 31, 2022	**21,243**	**2**	**166,647**	**(26)**	**(118,955)**	**47,668**
Issuance of common stock from employee stock plans	165	—	114	—	—	114
Stock-based compensation	—	—	3,563	—	—	3,563
Cumulative translation adjustment	—	—	—	(40)	—	(40)
Unrealized gain on marketable securities	—	—	—	74	—	74
Net loss	—	—	—	—	(40,157)	(40,157)
Balance as of December 31, 2023	**21,408**	**$ 2**	**$170,324**	**$ 8**	**$(159,112)**	**$ 11,222**

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,	
	2023	**2022**
Cash Flows from Operating Activities		
Net loss	$(40,157)	$ (62,984)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	52	54
Stock-based compensation	3,563	10,056
Amortization of right-of-use assets	863	885
Change in fair value of warrant liabilities	47	(6,303)
Net amortization of discounts on marketable securities	(630)	(292)
Changes in operating assets and liabilities:		
Prepaid and other current assets	1,228	(3,158)
Grant receivable	328	200
Other assets	(1,077)	1,372
Accounts payable	(1,568)	1,046
Accrued expenses	(2,168)	208
Lease liabilities	(934)	(738)
Other noncurrent liabilities	—	50
Net cash used in operating activities	(40,453)	(59,604)
Cash Flows from Investing Activities:		
Purchases of marketable securities	(11,821)	(42,978)
Sales and maturities of marketable securities	53,321	2,400
Net cash provided by (used in) investing activities	41,500	(40,578)
Cash Flows from Financing Activities:		
Proceeds from issuance of common stock from employee stock plans	114	280
Net cash provided by financing activities	114	280
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(40)	71
Net increase (decrease) in cash, cash equivalents and restricted cash	1,121	(99,831)
Cash, cash equivalents and restricted cash at beginning of year	11,733	111,564
Cash, cash equivalents and restricted cash at end of year	**$ 12,854**	**$ 11,733**
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ —	$ —
Cash paid for taxes	$ —	$ —

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

Vincerx Pharma, Inc.
Notes to Consolidated Financial Statements

December 31, 2023 and 2022

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 wars in Ukraine and Israel. 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 accounting principles generally accepted in the United States of America ("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., Vincerx Pharma GmbH and Vincerx Pharma Australia Pty Limited. All intercompany accounts and transactions have been eliminated.

Liquidity and Going Concern

As of December 31, 2023, the Company had approximately $12.8 million in cash and cash equivalents. The Company has incurred recurring operating losses and negative cash flows from operating activities since its inception and expects to continue to incur operating losses and negative cash flows in the future. Based on current business plans and assumptions, the Company believes that its existing cash and cash equivalents will be sufficient to fund its operating expenses and capital expenditure requirements into early third quarter 2024, although this estimate is based on plans and assumptions that may prove to be wrong, and the Company could use its available capital resources sooner than it currently expects. Accordingly, the Company will need to raise additional capital through public or private equity offerings, debt financings, collaborations and licensing arrangements, or other

sources, and such additional capital may not be available on favorable terms or at all, particularly in light of the current economic and market conditions. Market volatility resulting from pandemics or other epidemics, inflation and other economic and market conditions, the wars in Ukraine and Israel, the inability to maintain the listing on The Nasdaq Capital Market of the Company's common stock, and other factors could also adversely impact the Company's ability to raise additional capital. The failure to raise additional capital as and when needed or on acceptable terms would have a negative impact on the Company's financial condition and the ability to pursue its business strategy, and the Company may have to reduce its workforce or delay, reduce the scope of, suspend, or eliminate one or more preclinical programs, clinical trials, or future commercialization efforts, or curtail its business operations.

In accordance with Accounting Standards Update ("ASU") 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (Subtopic 205-40), the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about its ability to continue as a going concern for a period of one year after the date that its audited consolidated financial statements are issued. In light of the Company's existing cash resources and current and expected operating losses and negative cash flows, the Company will need additional capital prior to the one-year anniversary of the issuance of its consolidated financial statements, and such additional capital may not be available as and when needed on acceptable terms or at all. As a result, the Company has concluded that these circumstances and the uncertainties associated with its ability to obtain additional capital raise substantial doubt about the Company's ability to continue as a going concern for a period of one year after the date that its audited consolidated financial statements are issued.

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business, and do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of the uncertainties described above.

Revision of Previously Reported Consolidated Financial Statements

In connection with the preparation of the consolidated financial statements as of and for the year ended December 31, 2023, the Company identified an error in the computation of stock-based compensation that resulted in an overstatement of stock-based compensation of approximately $2.4 million for the year ended December 31, 2022. This error resulted from the erroneous inclusion of unvested forfeited awards that should have been excluded in the calculation of stock-based compensation. As a result, net loss for the year ended December 31, 2022 and the balances of accumulated deficit and additional paid in capital at December 31, 2022 were also overstated. The error did not impact the Company's cash flows from operating activities, financing activities and investing activities.

Management assessed the materiality of this presentation on prior period consolidated financial statements in accordance with SEC Staff Accounting Bulletin No. 99, "Materiality," codified in ASC 250, *Accounting Changes and Error Corrections* ("ASC 250"). Based on this assessment, management concluded that this error did not have a material impact on the prior period stated above. However, the amount of the prior period error in 2022 would have been material to the consolidated financial statements for fiscal year 2023 if the correction of the error was recognized in fiscal year 2023 or left uncorrected. Therefore, the Company has revised the prior

period financial statements impacted for this error. The impact of the revision on the 2022 consolidated financial statements is as follows:

	As of December 31, 2022		
	As Previously Reported	Revision	As Revised
Balance Sheet			
Stockholders' equity			
Preferred stock - $ 0.0001 par value	$ —	$ —	$ —
Common stock - $ 0.0001 par value	2	—	2
Additional paid-in-capital	169,030	(2,383)	166,647
Accumulated other comprehensive loss	(26)		(26)
Accumulated deficit	(121,338)	2,383	(118,955)
Total stockholders' equity	47,668	—	47,668
Total liabilities and stockholders' equity	$ 59,286	$ —	$ 59,286

	Year Ended December 31, 2022		
	As Previously Reported	Revision	As Revised
	(In thousands, except per share amounts)		
Statement of Operations and Comprehensive Loss			
Operating expenses	$ 73,574	$(2,383)	$ 71,191
Loss from operations	(73,574)	2,383	(71,191)
Other income (expense):			
Change in fair value of warrant liabilities	6,303	—	6,303
Interest income	664	—	664
Other income (expense), net	1,240	—	1,240
Total other income	8,207	—	8,207
Net loss	$ (65,367)	$ 2,383	$ (62,984)
Comprehensive loss	$ (65,372)	$ 2,383	$ (62,989)
Net loss per common share, basic and diluted	$ (3.11)	$ (0.11)	$ (3.00)
Weighted average common shares outstanding, basic and diluted	21,029	—	21,029

The impact of the revision on quarterly unaudited consolidated financial statements is as follows: stock-based compensation expense for the second and third quarters of 2022 were overstated by approximately $2.2 million and $0.3 million, respectively, and understated by approximately $0.1 million in the fourth quarter of 2022. Stock-based compensation for the first and second quarters of 2023 were understated by approximately $0.3 million and $0.4 million, respectively, and overstated by approximately $0.7 million in the third quarter of 2023.

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 consolidated 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 consolidated 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.

Reclassifications

Certain previously reported financial information has been reclassified to conform to the current period presentation. The impact of reclassifications was not significant to the prior year's overall presentation. These reclassifications had no effect on the reported results of operations.

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.

Restricted Cash

Restricted cash represents cash deposits with a financial institution in support of the Company's 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, plant and equipment are stated at cost, less accumulated depreciation and amortization. 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, 2023.

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, 2023 and 2022, 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 that such redemption rights could not be exercised during the first 12 months following the closing of the Business Combination unless the sales price of the Company's common stock had 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 notice of redemption), 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 were 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 sheets at fair value, with subsequent changes in their respective fair values recognized in the consolidated statements 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.

Leases

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) and non-lease components (e.g., common area maintenance, consumables). 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, 2023 and 2022, 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 2023 or 2022.

German Grant Income

In accordance with ASC 958, 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, 2023 and 2022 has been recorded in other income (expense), net on the consolidated statements of operations and comprehensive loss. The corresponding receivable is included within current assets and other assets, $1.0 million and $1.0 million, respectively, at December 31, 2023 on the consolidated balance sheet depending upon expectations for collection within twelve months of the balance sheet date.

Foreign Currency Translation and Transactions

The consolidated financial statements are presented in U.S. dollars. The functional currency for the Company's foreign subsidiaries is the local currency. 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 the Company's 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 the consolidated statements of operations and comprehensive loss.

Comprehensive Income or Loss

Comprehensive loss is equal to net loss, net foreign currency translation gain (loss), and net unrealized gain (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 November 2023, Financial Accounting Standards Board ("FASB") issued ASU No. 2023-07 "Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures." ASU 2023-07 requires incremental annual and quarterly disclosures about segment measures of profit or loss as well as significant segment expenditures. It also requires public entities with a single reportable segment to provide all segment disclosures required by the amendments in the update and all existing segment disclosures in Topic 280. The Company expects to adopt this guidance on January 1, 2025 on a retrospective basis and has yet to assess the impact to the consolidated financial statements.

In December 2023, FASB issued ASU No. 2023-09 "Income Taxes (Topic 740): Improvements to Income Tax Disclosures." ASU 2023-09 requires incremental annual disclosures around income tax rate reconciliations, income taxes paid and other related disclosures. This guidance requires prospective application and permits retrospective application to prior periods presented. The Company expects to adopt this guidance on January 1, 2025. The Company expects the adoption of this standard to result in increased disclosures in its notes to consolidated financial statements.

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 Vincera Pharma Common Stock was canceled, and the Legacy Holders received (i) 0.570895 shares of common stock, for each share of Legacy 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 Legacy Holders 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 Legacy Holders 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 Legacy Holders 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. During 2022 and 2023, the Company recorded $1.0 million in development milestones payable to Bayer in connection with the Company's IND filings for VIP236 and VIP943, respectively. 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, 2023			
	Level 1	**Level 2**	**Level 3**	**Total**
Assets:				
Cash Equivalents:				
Money market funds	$ 4,682	$ —	$—	$ 4,682
U.S. government treasuries	6,233	—	—	6,233
U.S. government agency securities	—	999	—	999
Total cash equivalents	$10,915	$ 999	$—	$11,914

	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 marketable securities at December 31, 2023. 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 years ended December 31, 2023 and 2022.

	Fair Value Measured as of December 31, 2023			
	Level 1	**Level 2**	**Level 3**	**Total**
Liabilities:				
Common stock warrant liabilities	$ —	$ —	$191	$ 191
Total fair value	$ —	$ —	$191	$ 191

	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

The estimated fair value of the warrant liability for the private warrants at December 31, 2023 and 2022 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, 2023. There were no transfers between Level 1, 2, or 3 during the years ended December 31, 2023 and 2022.

The following table presents changes in Level 3 liabilities measured at fair value for the years ended December 31, 2023 and 2022. 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, 2022	**$ 6,447**
Change in fair value	(6,303)
Balance – December 31, 2022	**144**
Change in fair value	47
Balance – December 31, 2023	**$ 191**

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, 2023 and 2022 is as follows:

	As of December 31, 2023	As of December 31, 2022
Stock price	$ 1.18	$ 1.02
Exercise price	$11.50	$11.50
Option term (years)	2.0	3.0
Volatility (annual)	90.9%	73.7%
Risk-free rate	4.2%	4.1%
Dividend yield (per share)	0%	0%

7. Available-For-Sale Securities

All marketable securities were considered available-for-sale at December 31, 2022. There were no marketable securities at December 31, 2023. 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

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, 2023 and 2022 (in thousands):

	December 31, 2023	December 31, 2022
Clinical related vendor prepayments	$407	$1,560
Payroll tax refund receivable	250	—
Other	127	369
	$784	$1,929

Property, plant and equipment, net consist of the following at December 31, 2023 and 2022 (in thousands):

	December 31, 2023	December 31, 2022	Estimated Useful Life
Furniture and fixtures	$ 236	$236	5 years
Computers	20	20	3-5 years
Total	256	256	
Less: accumulated depreciation	(131)	(79)	
Total property, plant and equipment, net	$ 125	$177	

Depreciation expense was approximately $52,000 and $54,000 for the years ended December 31, 2023 and 2022, respectively.

The following table sets forth the components of accrued expenses at December 31, 2023 and 2022, respectively (in thousands):

	December 31, 2023	December 31, 2022
Accrued payroll	$ 332	$ 297
Accrued bonus	—	2,042
Accrued benefits	918	923
Accrued manufacturing, clinical trial and related	505	661
	$1,755	$3,923

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, 2023, the Company had operating lease liabilities of approximately $2.5 million and right of use assets of approximately $2.2 million, which were included in the consolidated balance sheets.

In connection with the Company's 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 subleased substantially all of its 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 years ended December 31, 2023 and 2022 were $0.6 million and $0.3 million, respectively. The Company also received a $50,000 deposit, recorded as a noncurrent liability in the consolidated balance sheet at December 31, 2023.

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

	For the years ended December 31, 2023	December 31, 2022
Lease cost		
Operating lease cost	$1,196	$1,196
Variable lease cost	—	—
Total operating lease expense	$1,196	$1,196
Other information		
Operating cash flows from operating leases	$1,270	$1,048
Right-of-use assets obtained in exchange for operating lease liabilities	$ —	$ —
Weighted-average remaining lease term—operating leases	2.0	2.9
Weighted-average discount rate—operating leases	8%	8%

As of December 31, 2023, future minimum payments during the next three years are as follows (in thousands):

Year ended December 31, 2024	$1,320
Year ended December 31, 2025	1,372
Year ended December 31, 2026	28
Total	2,720
Less present value discount	(218)
Operating lease liabilities included in the Consolidated Balance Sheet at December 31, 2023	$2,502

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, 2023 and 2022, there were 21,407,510 shares and 21,242,884 shares of common stock outstanding, respectively, and no shares of preferred stock outstanding.

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 years ended December 31, 2023 and December 31, 2022.

During the years ended December 31, 2023 and 2022, 161,668 shares and 183,366 shares, respectively, were issued pursuant to the Company's Employee Stock Purchase Program ("ESPP") (see Note 11) for approximately $112,000 and $278,000 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, 2023, there was approximately $1,600 of unrecognized stock-based compensation related to restricted stock that will be amortized in 0.4 years.

A summary of restricted stock activity for the years ended December 31, 2023 and 2022 is presented below:

	Number of Shares	Weighted Average Grant Date Fair Value per Share
Nonvested at January 1, 2022	**182,686**	**$0.045**
Vested	(115,684)	—
Nonvested at December 31, 2022	**67,002**	**$0.065**
Vested	(48,940)	—
Nonvested at December 31, 2023	**18,062**	**$0.103**

Warrants

As of December 31, 2023, 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, 2023, the Company had 5,600,152 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, 2022	3,408	$18.74	10.0	$—
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	—
Options granted	1,131	1.22	—	—
Options exercised	(3)	0.82	—	—
Options cancelled	(262)	11.74	—	—
Outstanding at December 31, 2023	5,219	$ 8.74	8.1	$134
Options vested and exercisable at December 31, 2023	3,628	$11.25	7.8	$ 73

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.

As of December 31, 2023, the Company had stock-based compensation of approximately $0.7 million related to unvested stock options not yet recognized that are expected to be recognized over an estimated weighted average period of 0.6 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 years ended December 31, 2023 and 2022:

	For the years ended December 31,	
	2023	2022
Exercise price	$0.90	$3.30
Expected term (years)	5.6	5.8
Volatility (annual)	89.5%	85.1%
Risk-free rate	4.0%	2.8%
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,	
	2023	2022
Research and development	$1,712	$ 4,988
General and administrative	1,851	4,621
Restructuring	—	447
Total stock-based compensation expense	**$3,563**	**$10,056**

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 the Company's 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 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, 2023, 241,484 shares of common stock were reserved for future issuance under the ESPP. Shares issued under the ESPP were 161,668 and 183,366 shares for the years ended December 31, 2023 and 2022, respectively. The Company recorded approximately $133,000 and $278,000 of stock-based compensation expense for the years ended December 31, 2023 and 2022, 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, 2023 and 2022, respectively (amounts in thousands, except per share number):

	For the years ended December 31,	
	2023	2022
Numerator:		
Net loss	$(40,157)	$(62,984)
Denominator:		
Weighted average common shares outstanding, basic and diluted	21,295	21,029
Net loss per common share, basic and diluted	$ (1.89)	$ (3.00)

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,	
	2023	2022
Options outstanding	5,219	4,353
Warrants	3,295	3,295
Restricted stock	18	67
Total	8,532	7,715

13. Income Taxes

The Company has no provision for income taxes for the years ended December 31, 2023 and 2022. 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,	
	2023	2022
United States	$(35,281)	$(58,708)
International	(4,876)	(4,276)
	$(40,157)	$(62,984)

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,	
	2023	2022
Statutory federal income tax rate	21.0%	21.0%
State taxes, net of federal tax benefit	0.1%	0.7%
Change in fair value of warrant liabilities	— %	2.0%
Research and development	2.0%	(0.7%)
Other	0.5%	(0.1%)
Change in valuation allowance	(23.6%)	(22.9%)
Income taxes provision (benefit)	0.0%	0.0%

Significant components of the Company's net deferred tax assets as of December 31, 2023 and 2022, are as follows (amounts in thousands):

	As of December 31,	
	2023	2022
Deferred tax assets:		
Net operating loss	$ 15,475	$ 9,639
Stock-based compensation	5,235	5,025
Depreciation and amortization	—	4,198
Capitalized research and development	14,734	7,314
Research and development credit	2,231	1,635
Accruals and reserves	137	471
Lease liability	462	722
Total deferred income tax assets	38,274	29,004
Less: Valuation allowances	(37,748)	(28,360)
Deferred tax assets, net of valuation allowances	$ 526	$ 644
Deferred tax liabilities:		
Right of use asset	(526)	(644)
Total deferred income tax liabilities	$ (526)	$ (644)
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 $9.4 million and $12.9 million for the years ended December 31, 2023 and 2022, 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, 2023, 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, 2023, the Company had federal and state net operating loss carryforwards of approximately $59.2 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, 2023, the Company also has Federal and California research and development credits of $2.6 million and $1.1 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, 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
Increase/decrease due to prior year positions	—
Increase/decrease due to current year positions	259
Balance as of December 31, 2023	$1,238

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 2023 remain open to examination by the major taxing authorities. In addition, net operating losses arising from prior years are also subject to examination at the time they are utilized in future years. 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, 2023. 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.

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, 2023, 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, 2023 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.

(b) Trading Plans.

During the three months ended December 31, 2023, no director or officer adopted or terminated any contract, instruction, or written plan for the purchase or sale of securities of the Company pursuant to Rule 10b5-1(c) or any non-Rule 10b5-1 trading arrangement (as defined in Item 408(c) of Regulation S-K).

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, 2023 in connection with the solicitation of proxies for our 2024 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).
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	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).
4.6	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).
4.7	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).

Exhibit No.	Description
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).
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.
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).
97.1	Policy Relating to Recovery of Erroneously Awarded Compensation.

Exhibit No.	Description
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 29, 2024

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 29, 2024
/s/ Alexander A. Seelenberger Alexander A. Seelenberger	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 29, 2024
/s/ Laura I. Bushnell Laura I. Bushnell	Director	March 29, 2024
/s/ Dr. Brian J. Druker Dr. Brian J. Druker	Director	March 29, 2024
/s/ Dr. Raquel E. Izumi Dr. Raquel E. Izumi	Director	March 29, 2024
/s/ Dr. John H. Lee Dr. John H. Lee	Director	March 29, 2024
/s/ Francisco D. Salva Francisco D. Salva	Director	March 29, 2024
/s/ Dr. Ruth E. Stevens Dr. Ruth E. Stevens	Director	March 29, 2024

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