Table of Contents

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

FORM 10-K/A

(Mark One) **Amendment No. 1**

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

For the fiscal year ended December 31, 2020

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 **(State or Other Jurisdiction of Incorporation or Organization)**	**83-3197402** **(I.R.S. Employer Identification No.)**
260 Sheridan Avenue, Suite 400 **Palo Alto, CA** **(Address of principal executive offices)**	**94306** **(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
Units, each consisting of one share of Common Stock, $0.0001 par value per share, and one Warrant exercisable for one-half of one share of Common Stock at an exercise price of $11.50 per share	**VINCU**	**The Nasdaq Stock Market LLC**
Common Stock	**VINC**	**The Nasdaq Stock Market LLC**
Warrants	**VINCW**	**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. ☐

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, 2020) was approximately $7.8 million.

As of March 1, 2021, there were 13,984,441 shares (which include 1,801,399 shares of common stock constituting part of the units) of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2021 Annual Meeting of Stockholders, which will be filed with the United States Securities and Exchange Commission within 120 days of December 31, 2020, are incorporated by reference into Part III of this Annual Report on Form 10-K.

EXPLANATORY NOTE

On April 12, 2021, the Staff of the U.S. Securities and Exchange Commission (the "SEC") issued the "Staff Statement on Accounting and Reporting Considerations for Warrants Issued by Special Purpose Acquisition Companies ("SPACs")" (the "Staff Statement"). The Staff Statement clarified guidance for all SPAC-related companies regarding the accounting and reporting for their warrants that could result in the warrants issued by SPACs being classified as a liability measured at fair value, with non-cash fair value adjustments recorded in the statement of operations for each reporting period.

Vincerx Pharma, Inc. ("Vincerx" or the "Company") previously classified its private warrants and public warrants (collectively, the "warrants") as equity, consistent with market practice among SPACs, including Vincerx's predecessor company, LifeSci Acquisition Corp. ("LSAC"), prior to the business combination with VNRX Corp. (f/k/a Vincera Pharma, Inc.). The Company reviewed and discussed the accounting treatment of its warrants with WithumSmith+Brown, PC ("Withum"), its independent registered public accounting firm, its financial advisors and the audit committee of its board of directors and evaluated the applicability and potential impact of the Staff Statement on the Company's consolidated financial statements.

Following this review and evaluation, and after consulting with management, the Company's board of directors, upon the recommendation of the audit committee, concluded that, in light of the Staff Statement, (i) certain of the Company's private warrants should be accounted for as liabilities measured at fair value, with non-cash fair value adjustments recorded in the operating statement for each reporting period and (ii) the Company's audited consolidated financial statements for the year ended December 31, 2020 (the "Affected Period") should no longer be relied upon and should be restated due to the reclassification of these private warrants required for alignment with the Staff Statement. Further, any previously furnished or filed reports, earnings releases, guidance, investor presentations or similar communications regarding the restatement information for the Affected Period should also no longer be relied upon.

Accordingly, the Company is filing this Amendment No. 1 (this "Amended 10-K," "report" or "Report") to its Annual Report on Form 10-K for the year ended December 31, 2020 filed with the SEC on March 22, 2021 (the "Original Form 10-K") to restate its consolidated financial statements for the year ended December 31, 2020 to reflect the reclassification of these private warrants and to allocate offering costs to those warrants for the Affected Period. This restatement will result in non-cash, non-operating financial statement corrections for the Affected Period and will have no impact on the Company's cash position, operating expenses or cash flows or its ongoing operations or future plans.

This Amended 10-K also corrects an error on the cover page of the Original Form 10-K as to whether the Company (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, for which the correct box designated is yes.

The items amended in the Original Form 10-K are listed under "Items Amended by this Filing" below. Other than the "Items Amended by this Filing" and the correction in the immediately preceding paragraph, disclosures in the Original Form 10-K remain unchanged. However, for the convenience of the reader, this Amended 10-K restates in its entirety, as amended, the Original Form 10-K. The Company has not modified or updated disclosures presented in the Original Form 10-K, except as required to reflect the effects of the restatement. Accordingly, this Amended 10-K does not reflect events occurring after the filing of the Original Form 10-K and no attempt has been made in this Amended 10-K to modify or update other disclosures as presented in the Original Form 10-K, except as specifically referenced herein. This Amended 10-K should be read in conjunction with the Company's filings with the SEC subsequent to the filing of the Original Form 10-K.

Effect of Restatement and Revisions

As described above, as a result of the reclassification of certain of the private warrants to align with the Staff Statement, the Company is including in this Amended 10-K restated consolidated financial statements as of and

for the year ended December 31, 2020. The effect of the change in the accounting treatment of these private warrants and the resulting restatement of the Company's consolidated financial statements is (i) a 55% increase in the Company's accumulated deficit of approximately $5.9 million as of December 31, 2020, (ii) the reclassification of the initial fair value of these private warrants from additional paid-in capital to warrant liability within the consolidated balance sheet, (iii) the adjustment of other expense for the change in fair value of the warrant liability in the consolidated statements of operations and a corresponding adjustment to accumulated deficit for the year ended December 31, 2020 and (iv) the allocation of warrant offering costs that are now expensed. There was no impact on revenue, operating expenses or operating loss as the change in fair value of the warrant liability and warrant offering costs are presented within other expense and not as a component of operating loss in the consolidated statements of operations for the year ended December 31, 2020. The restatement of the consolidated financial statements for the year ended December 31, 2020 had no impact on the Company's liquidity or cash position. An explanation of the impact on the Company's consolidated financial statements is contained in "Note 3—Restatement of Consolidated Financial Statements" to the accompanying consolidated financial statements included in this Amended 10-K.

As all material restatement information will be included in this Amended 10-K, investors and others should rely only on the financial information and other disclosures regarding the restatement information for the Affected Period in this Amended 10-K and in future filings with the SEC (as applicable) and should not rely on any previously furnished or filed reports, earnings releases, guidance, investor presentations or similar communications regarding restatement information for the Affected Period.

Items Amended by this Filing

The following items included in the Original Form 10-K are amended by this Amended 10-K, in addition to the cover page:

- Part I – Item 1A. – Risk Factors
- Part II – Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operations
- Part II – Item 8 – Financial Statements and Supplementary Data
- Part II – Item 9A – Controls and Procedures
- Part IV – Item 15 – Exhibit and Financial Statement Schedules

As required by applicable rules of the SEC, new certifications by the Company's principal executive officer and principal financial officer are filed as Exhibits 31.1 and 31.2, and furnished as Exhibits 32.1 and 32.2, to this Amended 10-K.

TABLE OF CONTENTS

Forward-Looking Statements		1
Summary Risk Factors		3
PART I		5
ITEM 1.	Business.	5
ITEM 1A.	Risk Factors.	38
ITEM 1B.	Unresolved Staff Comments.	81
ITEM 2.	Properties.	81
ITEM 3.	Legal Proceedings.	81
ITEM 4.	Mine Safety Disclosures.	81
PART II		82
ITEM 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.	82
ITEM 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations.	83
ITEM 7A.	Quantitative and Qualitative Disclosures About Market Risk.	93
ITEM 8.	Financial Statements and Supplementary Data (As Restated).	94
ITEM 9.	Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.	115
ITEM 9A.	Controls and Procedures.	116
ITEM 9B.	Other Information.	117
PART III		118
ITEM 10.	Directors, Executive Officers and Corporate Governance.	118
ITEM 11.	Executive Compensation.	118
ITEM 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.	119
ITEM 13.	Certain Relationships and Related Transactions, and Director Independence.	119
ITEM 14.	Principal Accountant Fees and Services.	119
PART IV		119
ITEM 15.	Exhibit and Financial Statement Schedules.	119
ITEM 16.	Form 10-K Summary.	122
SIGNATURES		123

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,” “project,” “forecast,” “may,” “might,” “plan,” “possible,” “potential,” “predict,” “project,” “should,” “seeks,” “scheduled,” or “will,” and similar expressions are intended to identify forward-looking statements, and include but are not limited to:

- our future financial and business performance;
- strategic plans for our business and product candidates;
- our ability to develop or commercialize products;
- the expected results and timing of clinical trials and nonclinical studies;
- our ability to comply with the Bayer License Agreement;
- developments and projections relating to our competitors and industry;
- our expectations regarding our ability to obtain 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 Jumpstart Our Business Startups Act;
- our future capital requirements and the timing of those requirements and sources and uses of cash;
- our ability to obtain funding for our operations;
- 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 conducted prior to our in-licensing;
- risks related to the rollout of our business and the timing of expected business milestones;
- changes in the assumptions underlying our expectations regarding our future business or business model;
- our ability to develop and commercialize product candidates;
- general economic, financial, legal, political and business conditions and changes in domestic and foreign markets;
- changes in applicable laws or regulations;
- the impact of health epidemics, including the COVID-19 pandemic, on our business;
- the size and growth potential of the markets for our products, and our ability to serve those markets;
- market acceptance of our planned products;
- our ability to raise capital;

- the possibility that we may be adversely affected by other economic, business, and/or competitive factors; and
- other risks and uncertainties set forth in this report in the section entitled “Risk Factors.”

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

Forward-looking statements are subject to a number of risks and uncertainties that could cause actual results to differ materially from those expected. These risks and uncertainties include, but are not limited to, those risks discussed in Item 1A of this report. These forward-looking statements made by us in this report speak only as of the date of this report. Except as required under the federal securities laws and rules and regulations of the 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 2021 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).

- “Business Combination” means the Merger and the other transactions described in the Merger Agreement.
- “Lock-up Agreement” means those certain Resale Lock-up Agreements, dated December 23, 2020, by and between us and each Legacy Holder and each person or entity who acquired shares of our common stock in connection with the dissolution of the Sponsor.
- “Initial Qualified Financing” means an equity financing round that results in at least thirty million ($30,000,000) of gross proceeds.
- “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.
- “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.
- “Sponsor” means LifeSci Investments, LLC, LSAC’s sponsor and an entity affiliated with LifeSci Capital LLC, which was dissolved effective January 28, 2021.

- "Warrant Agreement" means that certain Warrant Agreement, dated March 5, 2020, between LSAC and the Continental Stock Transfer & Trust Company.

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 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 VIP152, VIP943, VIP924, VIP236 and our other current product candidates, raise capital or continue our operations.
- We rely on the preclinical and clinical trial data provided by Bayer in assessing the viability of our product candidates, and such preclinical and clinical trial data has not been verified by us or any independent third parties.
- Our business, operations and clinical development plans and timelines and supply chain could be adversely affected by the effects of epidemics, including the ongoing COVID-19 pandemic, on the manufacturing, clinical trial and other business activities performed by us or by third parties with whom we conduct business, including our contract manufacturers, contract research organizations, shippers and others.
- We are substantially dependent on the success of our lead product candidate, VIP152, which is currently in clinical trials. If we are unable to complete development of, obtain approval for and commercialize VIP152 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 and commercialize our product candidates on a timely basis or at all.
- There is currently no CDK9 inhibitor, ADC delivering a KSPi warhead or small molecule drug conjugate delivering a new chemical entity payload that has to date been approved by the U.S. Food and Drug Administration, or FDA, and the development of our product candidates may never lead to a marketable product.
- Our long-term prospects depend in part upon discovering, developing and commercializing additional product candidates, which may fail in development or suffer delays that adversely affect their commercial viability.
- 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 the final data.
- 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 or our strategic partners 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 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.
- Our business entails a significant risk of product liability and if we are unable to obtain sufficient insurance coverage such inability could have an adverse effect on our business and financial condition.
- Any product candidates we develop may become subject to unfavorable third party coverage and reimbursement practices, as well as pricing regulations.
- Clinical trials are expensive, time consuming, subject to delay 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 complete the development and commercialize any of our product candidates currently in preclinical and clinical development, should they succeed.
- We are at an early stage of development as a company and our limited operating history may make it difficult to evaluate our ability to succeed.
- We have incurred net losses since inception, and we expect to continue to incur significant net losses for the foreseeable future.
- 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 and/or eliminate one or more of our research and drug development programs or future commercialization efforts.
- The Bayer License Agreement obligates us to make significant milestone and royalty payments, some of which will be triggered prior to the commercialization of any of our other product candidates.
- We 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.
- We are a “controlled company” within the meaning of the Nasdaq listing rules and as such are exempt from certain corporate governance requirements.

PART I

ITEM 1. Business.

Corporate History and Background

We were initially formed on December 19, 2018 as a Delaware corporation formed 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 (defined below), 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, par value $0.0001 per share, or Legacy Vincera Pharma Common Stock, other than any Dissenting Shares (as defined in the Merger Agreement), was canceled and the Legacy Holders received (i) 0.570895 shares of our common stock, for each share of Legacy Vincera Pharma Common Stock held by them immediately prior to the effective time of the Merger and (ii) certain rights to additional shares of our common stock, or Earnout Shares, after the closing of the Business Combination.

The Legacy Holders are entitled to receive Earnout Shares after the closing of the Business Combination if the daily volume-weighted average price of our common stock equals or exceeds the following prices for any 20 trading days within any 30 trading-day period, or 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 Proxy Statement (as defined below)); (2) during any Trading Period prior to the six (6) 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 (8) 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% 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 Legacy Vincera Pharma Common Stock owned by them immediately prior to the closing of the Business Combination, and the remaining Earnout Shares that would otherwise have been issuable shall not be issuable to the Legacy Holders but in lieu thereof the number of authorized shares available for issuance under the Vincerx Pharma, Inc. 2020 Stock Incentive Plan shall be automatically increased by an equivalent number of shares of our common stock.

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

Further information regarding the Business Combination can be found in our Current Report on Form 8-K filed with the SEC on December 30, 2020 and the definitive proxy statement filed by the Company with the SEC on December 7, 2020, or the Merger Proxy Statement.

Overview

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

molecule drug program and (ii) a preclinical stage bioconjugation/next-generation ADC platform. We intend to use these product candidates to treat various cancers in a patient-specific, targeted approach. We believe that these product candidates are differentiated from current programs targeting similar cancer biology, and, if approved, may improve clinical outcomes of patients with cancer. References herein to preclinical and clinical studies regarding the Bayer assets refer to previous preclinical and clinical studies conducted by Bayer or other third parties before we in-licensed these assets.

Despite several decades of advances in targeted therapies, cancer continues to be the second leading cause of death in the United States population per the National Center for Health Statistics. Cancer is not a single disease but rather a constellation of maladies with each requiring a unique approach to vanquish it. Our vision is to address the unmet medical needs of patients with cancer with a diverse pipeline of targeted medicines. The small molecule drug program includes VIP152 (formerly known as BAY 1251152), which is a highly selective, clinical-stage PTEFb/CDK9 inhibitor. VIP152 may deliver value-generating data in the second half of 2021. Our ADC platform includes VIP943 (formerly known as BAY-943) and VIP924 (formerly known as BAY-924), which are next-generation ADC compounds addressing known and novel oncology targets that we believe could deliver a greater safety and efficacy profile than current ADC compounds. The bioconjugation program also includes VIP236, which is a SMDC for solid tumors. In addition to our lead products, we acquired the rights to additional product candidates that are still in the preclinical stage (e.g., VIP217, an oral PTEFb/CDK9 inhibitor).

PTEFb is an intracellular protein composed of two subunits, CDK9 and Cyclin-T. CDK9 is a transcriptional kinase that plays a central role in one of the processes that cancer cells use to survive and thrive: increased expression of cancer-promoting genes. Therapeutics directed at targeting CDK9 and the PTEFb complex have often been hindered by inhibition of alternative targets in the CDK family. These non-CDK9 targets diminish the therapeutic window of this drug class. Our lead product candidate, VIP152, is a potent and highly selective CDK9 inhibitor optimized for intermittent intravenous treatment, which (by decreasing activity of this kinase) disrupts PTEFb function. VIP152 has shown target modulation and preliminary signs of clinical activity in Phase 1, notably in patient populations with high unmet medical needs, which could lead to breakthrough therapy designation and accelerated approval for marketing in multiple indications in the United States.

Our SMDC platform targets advanced solid tumors with a potent cytotoxin (i.e., warhead, payload or toxophore). The warhead is designed to be released in the tumor stroma. Our most advanced SMDC (VIP236) has shown preclinical proof-of-concept across various in vivo human tumor models in mice.

Antibody-drug conjugates are an established therapeutic approach in oncology used to selectively deliver potent cytotoxins directly to tumor cells, with the goal of maximizing toxicity in tumor cells, while minimizing toxicity to healthy cells. The antibody component is designed to selectively bind to a distinct antigen preferentially expressed on tumor cells. Upon binding to the antigen, most ADC molecules are internalized by the cancer cell wherein the payload is released, causing cell death. Our next-generation ADC platform was engineered to specifically address efficacy and toxicity issues associated with currently approved ADCs. For example, our ADC platform has several key innovations regarding the linker (i.e., the chemical structure attaching the warhead to the antibody) and the warhead. Once our ADCs are internalized, our unique linker is specifically cleaved by an enzyme called, legumain. Legumain activity is elevated in cancer versus healthy cells; thereby preferentially targeting release of the warhead in cancer cells. In addition, our ADC platform is the first to use a KSPi as a payload to kill rapidly dividing cells. In clinical trials, KSPis that were administered systemically were found to be very toxic to rapidly dividing normal cells, such as blood and gastrointestinal cells; as such, they had a narrow therapeutic window, between killing normal versus cancer cells. By attaching our KSPi to antibodies directed against proteins found on cancer cells (e.g., CD123 and CXCR5), we increase the therapeutic window by selectively targeting tumor versus healthy cells. In addition, our KSPi is chemically designed to be impermeable to cell membranes. This innovation, referred to as the “Cell Trapper™,” increases the potency in cancer cells by trapping the warhead within the cancer cell. Once the cancer cell dies, the Cell Trapper prevents entry of the warhead into neighboring normal cells, thus reducing unwanted toxicity. We believe this combination of innovative technologies (i.e., antibody target; legumain-cleavable linker; KSPi and its Cell

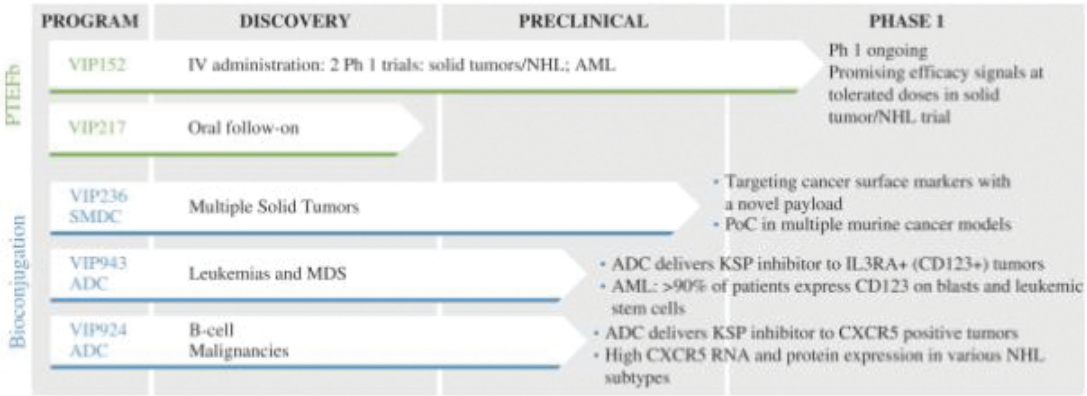
Trapper) has the potential to significantly minimize the side-effects and improve the therapeutic benefit of ADCs. Toxicity of ADCs to normal cells has been a major limitation, thus far, for the optimization of this therapeutic drug class. This platform, once validated, offers the potential for application with other tumor-specific therapeutic antibodies.

Our Strategy

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

- Continue the clinical development of our small molecule drug inhibitor (VIP152) in Phase 1 including expansions in patients with MYC- or MCL1-driven hematologic (e.g., double-hit DLBCL; transformed follicular lymphoma; Richter syndrome; chronic lymphocytic leukemia relapsed or refractory to any BTK inhibitors and venetoclax; and blastoid mantle cell lymphoma) and solid tumors (e.g., ovarian, triple negative breast cancer, and neuroendocrine-type castration resistant prostate cancer) to obtain clinical proof-of-concept in indications with unmet medical needs (and, by definition, potential accelerated approval indications) by the end of 2021.
- Begin clinical trials with our SMDC (VIP236) by the first half of 2022.
- Begin clinical trials with at least one of our next-generation ADCs (VIP943 or VIP924) between the end of 2022 through the beginning of 2024.

Our Product Candidate Pipeline



ADC = antibody-drug conjugate; AML = acute myeloid leukemia; MDS = myelodysplastic syndromes; NHL = nonHodgkin lymphoma; PoC = proof of concept; PTEFb = positive transcription elongation factor b; SMDC= small molecule drug conjugate

*Subject to effectiveness of Bayer License Agreement

Small Molecule Drug Program—PTEFb

VIP152 is a highly selective CDK9 inhibitor, which disrupts the function of PTEFb, designed to be administered intravenously and is in Phase 1 studies in patients with advanced cancer. VIP152 has broad intellectual property protection with exclusivity for composition of matter until at least 2033, plus potential extensions.

Scientific Overview of Oncogenes and Transcriptional Regulation in Cancer

Oncogenes (i.e., genes that drive cancer) are induced by mutations of normal genes that result in the loss of normal cell-growth control and lead to the formation of cancers. Expression of these oncogenes often requires

dysregulation of transcription (i.e., the biologic process by which genes are activated or regulated) and has been termed “transcriptional addiction.” Therefore, agents that can target the transcriptional machinery active in cancer cells may have significant utility in treating patients with cancer. Cyclin dependent kinases such as CDK7 and CDK9 control transcriptional initiation and elongation, respectively, suggesting that inhibition of these regulators of transcriptional activity may be very effective in controlling cancer. CDK9 also has recently been shown to phosphorylate BRG1 and inhibition of this kinase may have a role in re-expressing tumor suppressor genes silenced by epigenetic mechanisms in cancer.

The first-generation CDK inhibitors developed were relatively nonspecific and are often referred to as ‘pan-CDK’ inhibitors (e.g., flavopiridol and seliciclib) and also had non-CDK targets. Although these pan-CDK inhibitors showed great promise in preclinical models, they have proven to have a narrow range of doses that produces therapeutic response without causing significant adverse effects (i.e., narrow therapeutic index) in patients in clinical trials. After the generally disappointing results seen in clinical trials with non-selective CDK inhibitors, the importance of selectivity of compounds for specific CDKs; absence of alternative targets; and patient selection is now widely accepted. For example, three different CDK4/6 inhibitors (abemaciclib, palbociclib and ribocicilib) are now approved for the treatment of metastatic breast cancer. To date, no drugs specifically targeting CDK9 have been approved. However, there are several drugs in clinical trials targeting CDK9 such as dinaciclib, AZD5473, CYC065, alvocidib (formerly flavopiridol) and voruciclib. With regard to stage of clinical development, dinaciclib was evaluated in a Phase 3 trial of patients with relapsed or refractory chronic lymphocytic leukemia and demonstrated clinical activity, but did not complete registration studies due to program prioritization decisions by Merck & Co, Inc. Alvocidib (pan-CDK inhibitor) has been evaluated in Phase 2 trials in AML and has shown signs of clinical activity. VIP152 was designed to be a highly selective CDK9 inhibitor compared with other agents currently in clinical trials. We believe a highly selective CDK9 inhibitor will have a better therapeutic index than less selective inhibitors.

PTEFb/CDK9: A Potential Target for Oncology

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

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

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

Our lead small molecule drug candidate, VIP152, is designed as a highly selective CDK9 inhibitor, as shown below, designed to be administered intravenously. VIP152 binds to and blocks the phosphorylation activity of CDK9, thereby preventing PTEFb-mediated activation of RNA polymerase II and leading to the inhibition of transcription of various oncogenes. We believe this will cause cell death, which may lead to a reduction in tumor cell proliferation. VIP152 is in Phase 1 trials in patients with advanced cancer. In addition to the intravenous VIP152 molecule, we licensed from Bayer a follow-on oral molecule (VIP217), which is in the discovery stage.

The table below summarizes key in vitro features of VIP152. VIP152 inhibits CDK9 at low nanomolar concentrations even in presence of high ATP levels. In contrast, VIP152 does not inhibit other CDKs or kinases at physiologically relevant concentrations, except possibly IRAK1 and GSK3-alpha. When evaluated in a panel of 33 tumor cell lines, the median IC50 was 67 nM, suggesting broad anti-tumor activity.

IP152 Biochemical and Cellular Activity

Assay		VIP152
IC_{50} CDK9 (low ATP)		**3 nM**
IC_{50} CDK9 (high ATP)		**4 nM**
Selectivity against	**CDK2**	**730x**
	CDKs 1, 3, 4, 5, 6, 7, 8, 11	**[3]90x**
	Non-CDK kinases	**GSK3A: 6x IRAK1: 46x Others: >46x**
Proliferation inhibition in 33 tumor cell lines		**Median IC_{50} 67 nM**

Preclinical Results

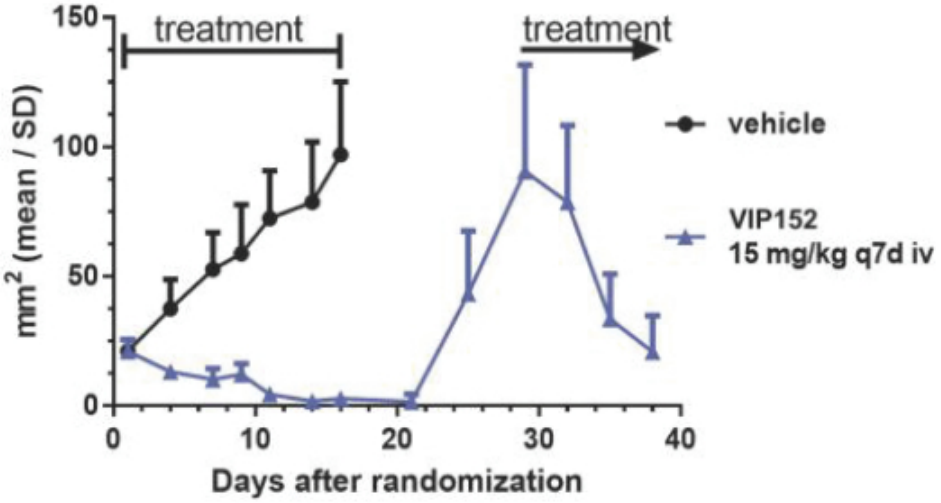
VIP152 Pharmacodynamics in a Multiple Myeloma Mouse Xenograft Model

The pharmacodynamic activity of VIP152 was assessed as a single-drug therapy (i.e., monotherapy) in mice implanted with human multiple myeloma tumors. In this study, a single dose of VIP152 was administered intravenously. After administration, a rapid reduction of MCL1 and MYC mRNA levels and a durable reduction of MYC protein levels were observed, which ultimately induced tumor cell death as marked by increases in processed caspase-3 and down-stream target cleaved PARP (i.e., markers of cell death by apoptosis).

VIP152 In Vivo Activity in a Double-Hit DLBCL Mouse Xenograft Model

The anti-cancer activity of VIP152 was assessed as a monotherapy in a mouse subcutaneous model of double-hit DLBCL. In this study, once weekly doses of VIP152 were administered intravenously. After administration, tumor regression was observed as shown below:

Weekly Infusions of VIP152 Cause Tumor Regression in Double-hit DLBCL (SU-DHL-10) Mouse Model



Clinical Trials

Study 18117: VIP152 Dose-escalation Study in Relapsed/ Refractory Leukemia

VIP152 was previously evaluated in an open-label, multicenter Phase 1 study, which intended to evaluate the safety, tolerability, preliminary anti-tumor activity, pharmacokinetics and MTD of VIP152 in patients with advanced hematologic malignancies. Such study was completed early with only 21 patients with relapsed/refractory AML treated (dose levels 5 to 30 mg; 21-day cycles; 30-minute infusions) due to inadequate monotherapy activity in an unselected AML patient population. A similar safety profile was observed across each of the four dose levels, with no DLTs reported—the most common adverse events included gastrointestinal side effects and cytopenia. No patients with other hematologic malignancies were included (e.g., CLL or MDS). Future studies for the treatment of leukemia will focus on select patient populations and mechanistic-directed combination strategies relevant for accelerated approval.

Study 17496: Target Validation and Early Clinical Signs of Efficacy

VIP152 is also being evaluated in an ongoing open-label Phase 1 dose-escalation study, which we refer to as Study 17496, designed to evaluate VIP152 as a monotherapy in patients with advanced cancer (i.e., solid tumors), including non-Hodgkin lymphoma, after failure of prior standard therapies to determine the safety, preliminary anti-tumor activity, tolerability, pharmacokinetics and MTD. As the trial is ongoing, none of the results summarized below are considered statistically significant.

Initial results from Study 17496 suggest that single agent VIP152 has a manageable safety profile, apparent dose-proportional pharmacokinetics and on-target pharmacodynamic activity. VIP152 has demonstrated tolerable side effects and a rapid reduction in MCL1 and MYC mRNA in peripheral blood cells. The initial signs of clinical benefit include:

- In a patient with double-hit DLBCL (GCB subtype) who had not responded to the last line of standard therapy (i.e., refractory), a durable complete metabolic response (per investigator assessment) was observed by PET-CT. This patient remained on treatment for 3.6 years.
- In a patient with previously treated pancreatic cancer and a patient with previously treated cystic adenoid salivary gland cancer, a prolonged disease control was observed.

Study 17496 enrolled 31 patients in the dose escalation portion of the study, then an expansion cohort for double-hit DLBCL was opened. To date, the double-hit DLBCL cohort has enrolled an additional 6 patients beyond the original 31 patients from the dose escalation. Notably, of the six patients who received VIP152 in the expansion, one additional patient with double-hit DLBCL achieved a complete metabolic response by PET-CT (per investigator assessment). This patient remained on treatment for 2.3 years.

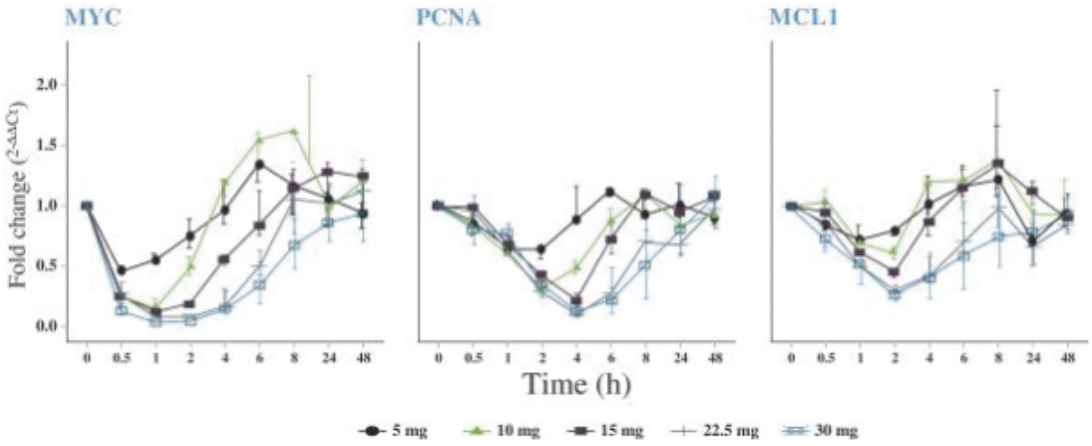
Double-hit DLBCL is a rare, aggressive (fast-growing) type of B-cell non-Hodgkin lymphoma caused by changes in the DNA that affect the MYC gene and either the BCL2 or BCL6 gene. Double-hit DLBCL is hard to treat and has a poor prognosis with a median progression-free survival of 11 months and median overall survival from diagnosis of 22 months. No standard treatments are currently approved for double-hit DLBCL, representing a population with an unmet medical need. Expansions in other tumor types driven by MYC and/or MCL1 are in planning.

VIP152 has demonstrated tolerable side effects in dose escalation. No treatment-related serious adverse effects or deaths were observed to date; however, two treatment-emergent deaths occurred that were unrelated to the VIP152. A total of 14 subjects experienced serious AEs: abdominal pain (three patients), dyspnea (two patients), hepatorenal syndrome, cholangitis, mastitis, device-related infection, sepsis, intestinal obstruction, pyrexia, urinary tract infection, blood bilirubin increased, esophageal metastasis cancer, hematuria, spinal operation, syncope and tumor pain (each with one patient). No patients withdrew from the study due to toxicity. Six patients required does reductions due to neutropenia. Seven patients received granulocyte colony-stimulating factor (i.e., growth factor support). Adverse events reported in more than 15% of patients are summarized below. Notably, no patients had grade ^{3}3 diarrhea as reported with other CDK inhibitors.

Study 17496: VIP152 Pharmacodynamics (Dose Escalation Portion)

The pharmacodynamic effects of VIP152 were evaluated in Study 17496. The results, from whole blood collected from patients on Cycle 1 Day 1, show a dose-dependent reduction in MYC and MCL1 mRNA as depicted below. Inhibition of cell proliferation was also observed as measured by PCNA expression.

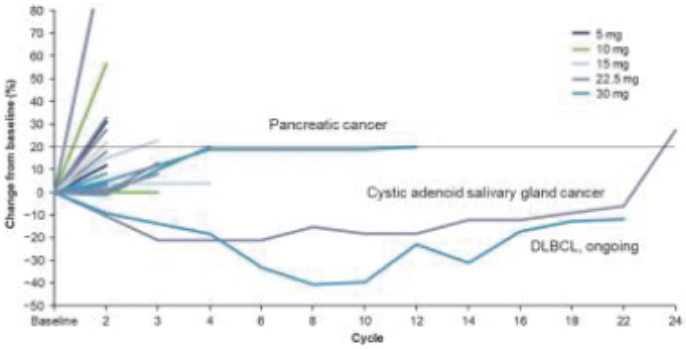
Study 17496: VIP152 Pharmacodynamic Activity in Patient Samples



Study 17496: Efficacy (Dose Escalation Portion)

The efficacy results of the dose-escalation portion of the study are summarized below. At the efficacious dose levels (i.e., 22.5 and 30 mg); two patients with solid tumors (one pancreatic cancer and one salivary gland cancer) had disease control for more than six cycles and, as mentioned above, one patient with double-hit DLBCL had a complete metabolic remission lasting more than three and half years per investigator assessment.

Study 17496: VIP152 Preliminary Efficacy in Dose Escalation
(Disease Control and Signs of Clinical Efficacy at □ 22.5 mg)



Efficacy	Total (*n*=31)
Best response, *n* (%)	
CR / PR#	1 (3)
Stable disease	10 (32)
Progressive disease	14 (45)
Not evaluated	6 (19)

#complete metabolic response (DLBCL)

Note: efficacy as reported per investigator assessment

Summary of PTEFb Inhibitor Program

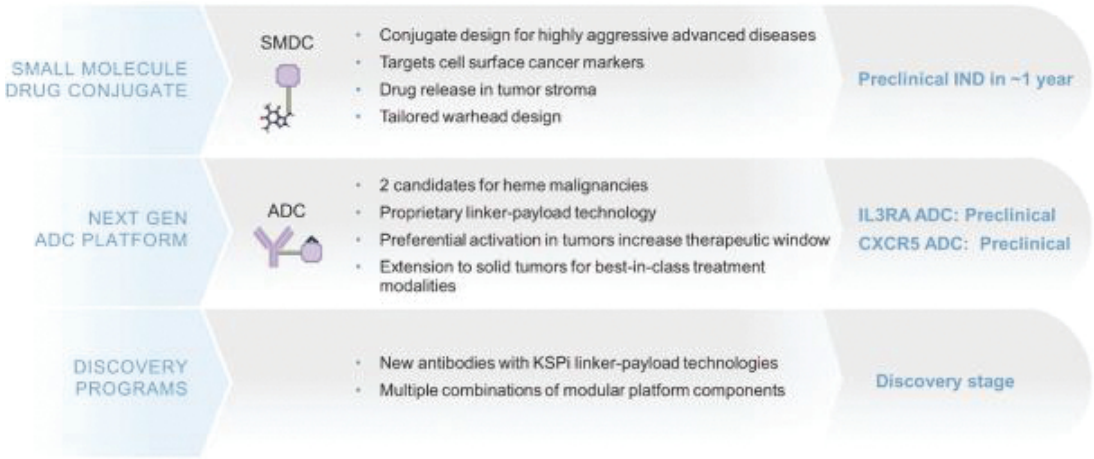
- *Mode of Action*: Highly selective CDK9 inhibitor, which produces rapid depletion of short-lived mRNAs of known oncogenes (e.g., MYC and MCL1).
- *Potential Indications*: MYC and MCL1 driven hematologic malignancies and solid tumors including monotherapy and combination studies.

- *Clinical Status*: MTD has been determined in Phase 1; safety, pharmacokinetics, pharmacodynamics and early signs of efficacy support further development with currently available drug substance and drug product.
- *Intellectual Property*: Broad intellectual property protection until at least 2033.
- *Discovery*: Oral follow-on opportunity.

Our Bioconjugation Platform

We have obtained from Bayer an exclusive license for a proprietary and innovative bioconjugation platform that we believe will leverage years of Bayer discovery know-how into innovative treatment modalities. The licensed platform includes a next generation ADC platform comprised of two preclinical-stage assets for hematology-oncology (IL3RA (also known as CD123) ADC and CXCR5 ADC) and an SMDC for solid tumors.

Our Proprietary Bioconjugate Platforms—Shaping the Future

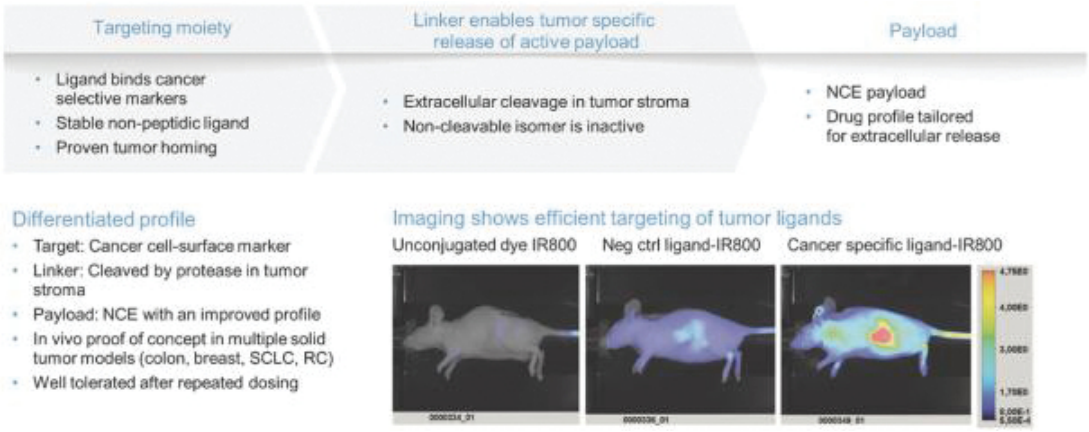


Innovative SMDC platform

To improve the tumor selectivity of cytotoxic agents, our small molecule drug conjugates (SMDCs) use two methods of targeted delivery: binding to a_vb_3 and drug release mediated by enzymatic cleavage. VIP236, our lead candidate, consists of an a_vb_3 integrin binder and a linker that is cleavable by neutrophil elastase. The payload is a modified camptothecin derivative designed for extracellular release. The payload displays high cellular permeability, and in contrast to SN38, the active metabolite of irinotecan, it is not a substrate of efflux transporters. The conjugate is highly efficacious *in vivo* effecting tumor regressions in SW480 (colon cancer), MX1 (breast cancer) and NCI-H69 (lung cancer) xenograft models with T/C ratios of 0.1, 0.03 and 0.06 ($p<0.05$ each, compared to vehicle control), respectively, and it shows very good tolerability. Initial pharmacokinetic studies in tumor

bearing mice demonstrate a more than 10-fold improved tumor/plasma ratio of free toxophore when administered as a conjugate as compared with direct administration of unconjugated toxophore (see figure below).

VIP236: SMDC with Tumor Stroma Activated Conjugate



Abbreviations: NCE = new chemical entity; RC = renal cancer; SCLC = small cell lung cancer

Next-generation ADC technology

ADCs are a validated therapeutic approach in oncology used to selectively deliver a highly potent payload directly to tumors thereby minimizing toxicity to surrounding healthy tissue. Upon binding to the tumor cell antigen, the ADC is internalized by the tumor cell and the payload is released intracellularly, killing the cell in a targeted manner. To date, eight ADCs have been approved by the FDA, with three approvals in 2019-2020.

Despite the promise of ADCs, the challenge of optimizing the balance between efficacy and tolerability (i.e., therapeutic index or therapeutic window) has limited their broad potential as treatments for cancer. Our proprietary and innovative bioconjugation platform was engineered to specifically address toxicity issues plaguing current ADCs. The payload classes currently used are confined to microtubule destabilizers (e.g., auristatin, dolastatin, maytansinoid and tubulysine), DNA interacting agents (e.g., calicheamicin, duocarmycin, PBD and IGN) and topoisomerase inhibitors (e.g., exatecan). Many of these permeable payloads and/or highly potent DNA-interacting payloads have safety issues and, therefore, result in an insufficient therapeutic index.

Our next-generation ADC platform was engineered to deliver on the promise of ADCs as follows:

Our Next Generation ADC Technology Solutions

Problems of ADCs	NextGen Design Features [1]	Impact/Benefits
High-potency payloads have narrow therapeutic index	**KSP inhibitor** is a novel payload class in ADCs	**Low/no toxicity** in non-dividing cells, no neurotoxicity **High potency** and **novel MoA** **Flexibility**, compatible with different linker designs
Off-target toxicities due to leaking and unspecific cleavage of highly toxic, cell-permeable toxophores	**Stable linker specifically cleaved by legumain**, a tumor associated protease **Impermeable payload – Cell Trapper™** attached to KSPi to reduce membrane permeability	**Unique cleavage sequence** post Asn (no unspecific cleavage) **Second level of tumor targeting** via specific ADC activation **Safety:** No unspecific uptake of released payload in healthy cells **Efficacy:** High and long-lasting tumor accumulation
Highly lipophilic payloads cause aggregation and unspecific pinocytosis of ADCs	**KSPi payload with Cell Trapper™** is hydrophilic and does not cause aggregation	**Safety:** No side effects associated with aggregation **Efficacy:** Allows for DAR of 6 without affecting PK **CMC:** Less risk for reduced shelf live & particle formation

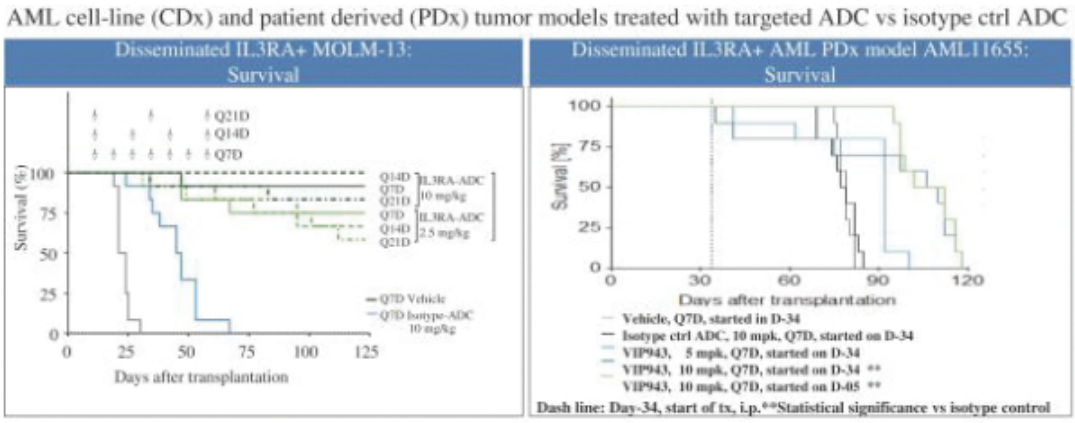
Abbreviations: ADC = antibody-drug conjugate; Asn = asparagine (peptide); DAR = drug-antibody ratio; KSPi = kinesin spindle protein inhibitor; MoA = mechanism of action; PK = pharmacokinetics

We are the first company to use a KSPi as a payload. Kinesin spindle protein is a motor protein responsible for an essential event in mitosis, the segregation of duplicated centrosomes during spindle formation in the G2/M phase of the cell cycle, and is, therefore, required for productive cell divisions. High expression of kinesin spindle protein in hematologic indications such as AML blasts, DLBCL and in solid cancers such as breast, bladder and pancreatic cancer has been linked to poorer prognosis, and thus, kinesin spindle protein presents an attractive target for cancer treatment. Kinesin spindle protein is active in all proliferating cells; therefore, KSPis, representing various structural classes, have resulted in neutropenia, mucositis and stomatitis in clinical trials. To date, these limitations have prevented approval of KSPis as cancer therapies, when administered systemically. However, tumor targeting with an impermeable KSPi overcomes the narrow therapeutic index of systemically administered agents by ensuring kinesin spindle protein is only inhibited in cancer cells and not in neighboring healthy tissue. We have two KSPi-ADCs, VIP943 and VIP924, in preclinical development for the treatment of hematologic malignancies:

- VIP943 is an anti-IL3RA-KSPi ADC
- VIP924 is an anti-CXCR5-KSPi ADC

VIP943 and VIP924 have shown preclinical proof-of-concept in vivo human leukemia and lymphoma tumor models in mice as shown below:

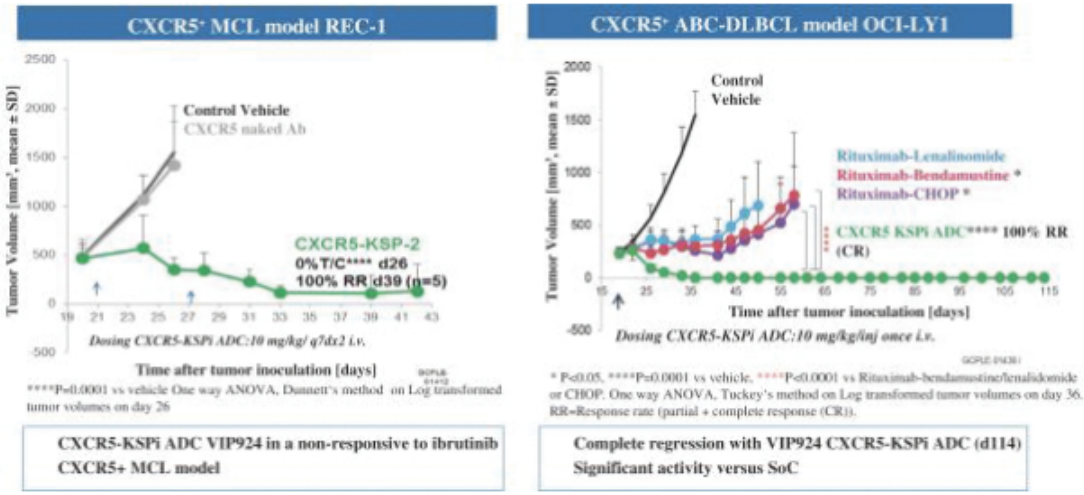
VIP943: IL3RA-KSPi ADC
Increases Survival in AML Models



- Increased survival in disseminated IL3RA-positive AML CDx model MOLM-13, treated Q7Dx7
- High selectivity of targeted vs. isotype control ADC
- Increased survival in disseminated IL3RA-positive AML PDx model, treated Q7D and reduction of AML tumor burden
- High selectivity of targeted vs. isotype control ADC

Abbreviations: ADC = antibody-drug conjugate; AML = acute myeloid leukemia; ctrl = control; Q7D = every 7 days; Q14D = every 14 days; Q21D = every 21 days

VIP924 Induces Sustained Tumor Regression Compared with
Standard Therapy in DLBCL & MCL Models



CXCR5-KSPi ADC VIP924 in a non-responsive to ibrutinib CXCR5+ MCL model

Complete regression with VIP924 CXCR5-KSPi ADC (d114)
Significant activity versus SoC

VIP943—IL3RA-KSPi ADC

Targeting IL3RA

IL3RA is the α-subunit of the IL-3 receptor. IL-3 is a protein, mainly produced by activated T cells, which regulates the function and production of immune cells by binding to the IL-3 receptor. IL3RA is expressed at high levels in AML, classical Hodgkin lymphoma, blastic plasmacytoid dendritic cell neoplasms and myelodysplastic syndromes. Importantly, IL3RA overexpression on AML blasts has been associated with an increased number of leukemic blast cells at diagnosis and with a negative prognosis.

Several studies have indicated that IL-3 and its receptor play important roles in the progression of AML, and indeed, experiments with a monoclonal antibody that blocks the binding of IL-3 to IL3RA have shown increased survival in AML mouse models. Characterization of hematologic malignancies has demonstrated increased IL3RA expression in AML blasts as compared with normal cells. Furthermore, these IL3RA-overexpressing cells have been shown to be able to initiate and maintain the leukemic process in immuno-deficient mice and thus act as leukemic stem cells. Consequently, IL3RA has been shown to be a useful biomarker for the detection of minimal residual disease, thereby predicting relapse in patients with AML. Taken together, these results suggest that IL3RA is a viable target for an ADC approach for the treatment of AML and other IL3RA-positive hematologic malignancies (e.g., MDS, chronic myelogenous leukemia, and blastic plasmacytoid dendritic cell neoplasm).

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

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

These preclinical findings underscore the differentiation of the KSPi-ADC platform compared with currently approved ADCs for hematologic malignancies, as the observed clinical toxicities were predicted in the preclinical models as outlined below:

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

	MYLOTARG™	BESPONSA®	POLIVY™	ADCETRIS®	KSPi ADC Platform		
Preclinical Target Organ Tox					(Cynos)		
Bone marrow/ lymph nodes	+	+	+	+	-		
Liver	+	+	+	+	-		
Clinical Trial Severe Adverse Events					Linker	KSPi	Cell trapper
Myelosuppression		++	++	++	O	O	O
Infections/PML			++	+++	O	O	O
Hepatotoxicity/ VOD	+++	+++	++	++	O		O
Peripheral neuropathy			++	++		O	

Abbreviations:
GI: gastrointestinal; PML: Progressive multifocal leukoencephalopathy; VOD: veno-occlusive disease
-: Not present, +: Present, ++: Warnings & precautions, +++: Black box warning
O: Designs to address AEs
Source: Drugs@FDA

Summary of Next-generation KSPi-ADC Platform

- Despite recent approvals, currently approved ADCs have a narrower than expected therapeutic index, which limits wider use (e.g., toxicity prevents reaching maximally efficacious dose or severe overlapping toxicities, such as neutropenia, with standard of care).
- Three key features of the KSPi-ADC platform were engineered to deliver on the promise of ADCs:
  - Antibodies against overexpressed tumor antigens (i.e., anti-IL3RA for leukemias and anti-CXCR5 for B-cell malignancies);
  - A nonpermeable and potent warhead (i.e., hydrophilic KSPi) to prevent “bystander effect” on healthy cells (i.e., warhead accumulates in targeted cancer cells but cannot get into healthy cells); and
  - A novel linker preferentially cleaved in tumor tissue vs normal cells (i.e., linker only cleaved by legumain, an enzyme over expressed in tumor tissue).
- Preclinical results for the KSPi-ADCs show efficacy without associated toxicity observed with the ADCs approved to date (e.g., monkey studies with the VIP943 showed no neutropenia, thrombocytopenia or liver toxicity).
- IND enabling studies for the KSPi-ADCs are in planning.

Sales and Marketing

Because we are a clinical-stage company, we do not currently have our own marketing, sales or distribution capabilities. To commercialize VIP152 or any future product candidate, if approved for commercial sale and marketing, we would have to develop a sales and marketing infrastructure. We may opportunistically seek strategic collaborations or partners to maximize the commercial opportunities for VIP152 or any future 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 VIP152, and there are a limited number of manufacturers that operate under the cGMP requirements of the FDA that might be capable of manufacturing for us. We currently intend to rely on contract manufacturing organizations, for both drug substance and drug product. In addition, we intend to recruit highly qualified personnel with experience to manage the contract manufacturing organizations producing our product candidates and other product candidates that we may develop in the future. Similarly, we do not own or operate a laboratory with expertise in diagnostic assessment of cancer subpopulations and will contract with specific commercial diagnostic labs on trials performed to assure a companion diagnostic(s) is available to accompany our therapeutic product. We will recruit highly qualified personnel with experience to manage these commercial diagnostic companies for our product candidates or those that we may develop in the future.

Our outsourced approach to manufacturing relies on contract manufacturing organizations to first develop cell lines and manufacturing processes that are compliant with cGMP requirements and then produce material for preclinical studies and clinical trials. Our agreements with contract manufacturing organizations may obligate them to develop a production cell line, establish master and working cell banks, develop and qualify upstream and downstream processes, develop drug product processes, validate (and in some cases develop) suitable analytical methods for test and release as well as stability testing, produce drug substance for preclinical testing, produce cGMP-compliant drug substance or produce cGMP-compliant drug product. We will conduct audits of contract manufacturing organizations prior to initiation of activities under these agreements and monitor operations to ensure compliance with the mutually agreed process descriptions and cGMP regulations. A similar approach is applied to commercial diagnostic companies that we would partner with for companion diagnostics.

Competition

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

Many global pharmaceutical companies, as well as medium and small biotechnology companies, are pursuing new cancer treatments whether small molecules, biologics, ADCs, and 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.

PTEFb Platforms

Our PTEFb inhibitors work by targeting the CDK9 of the PTEFb heteroduplex made up of CDK9 and Cyclin-T. To our knowledge, there are at least six other CDK9 programs in development demonstrating clinical efficacy and several are more advanced than our programs. The companies with clinical-stage programs include Merck & Co., Inc., Astra-Zeneca PLC, Cyclacel Pharmaceuticals Inc., Sumitomo Dainippon Pharma Co., Ltd., Tolero Pharmaceuticals, Inc. and MEI Pharma, Inc. These companies and their current or future partners may develop CDK9 inhibitor programs with attributes to compete in the same indications as our current and future PTEFb product candidates. We expect to compete on efficacy, safety and tolerability, and if our products are not demonstrably superior in these respects compared with other approved therapies, we may not be able to compete effectively.

Bioconjugation Platforms

We believe our bioconjugation platform components are well differentiated and provide us the flexibility of creating ADCs, SMDCs or other variants thereof to address specific needs to address individual diseases. Although our KSPi and the new ADC programs we have underway are proprietary and, in our view highly differentiated, many companies continue to invest in innovation in the ADC field including new payload classes, new conjugation approaches, and new targeting moieties. Any of these initiatives could lead to a platform that has superior properties to ours. We are aware of multiple companies with ADC technologies that may be competitive to our ADC platforms, including Astellas Pharma Inc., Astra-Zeneca PLC, Bristol-Myers Squibb Company, Daiichi Sankyo Company, Limited, ImmunoGen, Inc., Immunomedics, Inc., Mersana Therapeutics Inc., CytomX Therapeutics, Inc., Pfizer, Inc. and Seattle Genetics, Inc. These companies or their partners, including AbbVie Inc., Genentech, Inc., Eli Lilly and Company, Novartis International AG, Sanofi S.A. and Takeda Pharmaceutical Company Limited, may develop ADCs, SMDCs or related bioconjugation products based on the unique capabilities of each technology to compete in the same indications as our current and future bioconjugation product candidates. We expect to compete on improved efficacy, safety and tolerability compared with other ADCs or SMDCs. However, if our products are not demonstrably superior compared with other approved therapeutics, we may not be able to compete effectively rendering our technologies, or our drug candidates, obsolete or non-competitive.

Many of our potential competitors, either alone or in partnership with other players, may have significantly greater financial, technical and human resource capabilities than our company. This in turn might allow them to become more successful than us in achieving treatment approvals and market acceptance, reducing the competitiveness of our treatments and accelerating their obsolescence. A continued trend showing strong mergers and acquisitions 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 site and patient registration for clinical trials, as well as in the attainment of technologies that might be complementary or necessary for our clinical programs.

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

Government Regulation

The FDA and other regulatory authorities at federal, state and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of small molecule drugs and biologics such as those we are developing. We, along with third party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of or current product candidates or any future product candidate.

FDA Drug Approval Process

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug and Cosmetic Act, or FDCA, and other federal and state statutes and regulations govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling and import and export of pharmaceutical products. Biological products used for the prevention, treatment or cure of a disease or condition of a human being are subject to regulation under the FDCA, except the section of such Act that governs the approval of new drug applications, or NDAs. Biological products, such as our ADC product candidates, are approved for marketing under provisions of the Public Health Service Act, via a Biologics License Application, or BLA. However, 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 as drugs. 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 or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution.

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

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's current Good Laboratory Practices regulations;
- submission to the FDA of an IND, which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;
- approval by an Institutional Review Board or ethics committee at each clinical site before the trial is commenced;
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, good clinical practice requirements and other clinical trial-related regulations to establish the safety, purity and potency of the proposed drug 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 that includes substantial evidence of safety, purity and potency from results of nonclinical testing and clinical trials; satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of an NDA/BLA to file the application for review;
- satisfactory completion of one or more FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMP requirements and to assure that the facilities, methods and controls are adequate to preserve the drug product'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 product for particular indications for use in the United States.

Preclinical and Clinical Development

Prior to beginning the first clinical trial with a product candidate 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 new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology and pharmacodynamic characteristics of the product candidate; chemistry, manufacturing and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold until the IND sponsor and the FDA resolve the outstanding concerns or questions. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with good clinical practices, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. 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 trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries. For purposes of NDA/BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

- *Phase 1*—The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism, distribution and elimination of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. In the

case of some products for severe or life-threatening diseases, such as cancer, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients with active malignancy for whom other therapy is not available.

- *Phase 2*—The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- *Phase 3*—The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

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

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

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

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug. In addition, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

While the IND is active and before approval, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or in vitro testing suggesting a significant risk to humans and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

U.S. Submission, Review and Approval

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

Once an NDA/BLA has been submitted, the FDA's goal is to review standard applications within ten months after it accepts the application for filing (a 60-day process), or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process can be significantly extended by FDA requests for additional information or clarification. The FDA reviews an NDA/BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions.

Before approving an NDA/BLA, the FDA will typically inspect the facility or 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 product within required specifications. Additionally, before approving an NDA/BLA, the FDA will typically inspect one or more clinical sites to assure compliance with Good Clinical Practices. 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 investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response letter will describe all of the deficiencies that the FDA has identified in the NDA/BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response letter without first conducting required inspections, testing submitted product lots and/or reviewing proposed labeling. In issuing the Complete Response letter, the FDA may recommend actions that the applicant might take to place the NDA/BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of an NDA/BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the NDA/BLA with a Risk Evaluation and Mitigation Strategy to ensure the benefits of the product outweigh its risks. A Risk Evaluation and Mitigation Strategy is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance

with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies. In addition, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could impact the timeline for regulatory approval or otherwise impact ongoing development programs.

In addition, the Pediatric Research Equity Act, or PREA, requires a sponsor to conduct pediatric clinical trials for most drugs, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs/BLAs and supplements must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be 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 fails to submit a request for approval of a pediatric formulation.

Expedited Development and Review Programs

Any marketing application for a drug product submitted to the FDA for approval may be eligible for FDA programs intended to expedite the FDA review and approval process, such as priority review, fast track designation, breakthrough therapy designation and accelerated approval.

A product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or to provide a significant improvement in the treatment, diagnosis or prevention of a serious disease or condition compared to marketed products. For products containing new molecular entities, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date (compared with ten months under standard review).

To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical needs by providing a therapy where none exists or a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. Fast track designation provides opportunities for frequent interactions with the FDA review team to expedite development and review of the product. The FDA may also review sections of the NDA/BLA for a fast track product on a rolling basis before the complete application is submitted, if the sponsor and FDA agree on a schedule for the submission of the application sections, and the sponsor pays any required user fees upon submission of the first section of the NDA/BLA. The review clock does not begin until the final section of the NDA/BLA is submitted.

In addition, under the provisions of the Food and Drug Administration Safety and Innovation Act passed in July 2012, a sponsor can request designation of a product candidate as a "breakthrough therapy." A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs or biologics designated as breakthrough therapies are also eligible for accelerated approval. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy.

Additionally, products studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval, pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review 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, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that drug or biologic.

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

If a product that has orphan designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan exclusivity, which means that the FDA may not approve any other applications, including a full NDA/BLA, to market the same product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan exclusivity does not prevent FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA/BLA application fee.

A designated orphan product may not receive orphan exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to quality control and quality assurance, record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There are

also continuing user fee requirements, under which FDA assesses an annual program fee for each 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 third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP requirements and other aspects of regulatory compliance.

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

- restrictions on the marketing or manufacturing of a product, mandated modification of promotional materials or issuance of corrective information, issuance by FDA or other regulatory authorities of safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product, or complete withdrawal of the product from the market or product recalls;
- fines, warning or untitled 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 product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products; or
- injunctions, consent decrees or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of drug products. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe 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. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Marketing Exclusivity

Market exclusivity provisions authorized under the FDCA can delay the submission or the approval of certain marketing applications. 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. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not approve or even accept for review an ANDA or an NDA submitted under Section 505(b)(2), or

505(b)(2) NDA, submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original 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 investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) 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 effectiveness.

Pediatric exclusivity is another type of marketing exclusivity available 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 the described clinical trials. In addition, orphan drug exclusivity, as described above, may offer a seven-year period of marketing exclusivity, except in certain circumstances.

Biosimilars and Reference Product Exclusivity

The Affordable Care Act, signed into law in 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-approved reference biological product. To date, a number of biosimilars have been licensed under the BPCIA, and numerous biosimilars have been approved in Europe. The FDA has issued several guidance documents outlining its approach to the review and approval of biosimilars.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

Complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

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 product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant’s own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars

approved as interchangeable products. At this juncture, it is unclear whether products deemed “interchangeable” by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

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 ultimate impact, 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 other divisions of the U.S. Department of Health and Human Services (such as the Office of Inspector General, Office for Civil Rights and the Health Resources and Service Administration), the U.S. Department of Justice and individual U.S. Attorney offices within the Department of Justice, and state and local governments. For example, our clinical research, sales, marketing and scientific/educational grant programs 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, each as amended, as applicable. Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors and customers may be subject to healthcare laws, regulations and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which our conducts its business. Such laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security, price reporting and physician sunshine laws. Some of our pre-commercial activities are subject to some of these laws.

The federal anti-kickback statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The anti-kickback statute has been interpreted to apply to arrangements between therapeutic product manufacturers on one hand and prescribers, purchasers and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor.

Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the anti-kickback statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor.

Additionally, the intent standard under the anti-kickback statute was amended by the Patient Protection and Affordable Care Act to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Violations of the anti-kickback statute can result in significant civil and criminal fines and penalties, imprisonment and exclusion from federal healthcare programs. In addition, the Affordable Care Act codified case law that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act.

The federal false claims and civil monetary penalty laws, including the federal False Claims Act, which imposes significant penalties and can be enforced by private citizens through civil qui tam actions, prohibit any

person or entity from, among other things, knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to, or approval by, the federal government, including federal healthcare programs, such as Medicare and Medicaid, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government, or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government. A claim includes “any request or demand” for money or property presented to the U.S. government. For instance, historically, pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies’ marketing of the product for unapproved, off-label, and thus generally non-reimbursable, uses. Penalties for federal civil False Claims Act violations may include up to three times the actual damages sustained by the government, plus significant mandatory civil penalties, and exclusion from participation in federal healthcare programs.

HIPAA created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the anti-kickback statute, the Affordable Care Act amended the intent standard for certain healthcare fraud statutes under HIPAA such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

We may be subject to data privacy and security regulations by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and its implementing regulations, imposes requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, the Health Information Technology for Economic and Clinical Health Act makes HIPAA’s privacy and security standards directly applicable to business associates, which are independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. The Health Information Technology for Economic and Clinical Health Act also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys’ fees and costs associated with pursuing federal civil actions. In addition, many state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways, are often not pre-empted by HIPAA, and may have a more prohibitive effect than HIPAA, thus complicating compliance efforts.

Additionally, the federal Physician Payments Sunshine Act within the Affordable Care Act, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) report annually to the Centers for Medicare and Medicaid Services information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members. Failure to report accurately could result in penalties. In addition, many states also govern the reporting of payments or other transfers of value, many of which differ from each other in significant ways, are often not pre-empted, and may have a more prohibitive effect than the federal Physician Payments Sunshine Act, thus further complicating compliance efforts. Many states have similar statutes or regulations to the above federal laws that may be broader in scope and may apply regardless of payor. We may also be subject to state laws that

require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, and/or state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, drug pricing or marketing expenditures. These laws may differ from each other in significant ways and may not have the same effect, further complicating compliance efforts. Additionally, to the extent that we have business operations in foreign countries or sells any of our products in foreign countries and jurisdictions, including Canada or the E.U., we may be subject to additional regulation.

We may develop products that, once approved, may be administered by a physician. Under currently applicable U.S. law, certain products not usually self-administered (including injectable drugs) may be eligible for coverage under Medicare through Medicare Part B. Medicare Part B is part of original Medicare, the federal health care program that provides health care benefits to the aged and disabled, and covers outpatient services and supplies, including certain biopharmaceutical products, that are medically necessary to treat a beneficiary's health condition. As a condition of receiving Medicare Part B reimbursement for a manufacturer's eligible drugs, the manufacturer is required to participate in other government healthcare programs, including the Medicaid Drug Rebate Program and the 340B Drug Pricing Program. The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter and have in effect a national rebate agreement with the Secretary of Department of Health and Human Services as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. Under the 340B Drug Pricing Program, the manufacturer must extend discounts to entities that participate in the program.

In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. It is difficult to predict how Medicare coverage and reimbursement policies will be applied to our products in the future and coverage and reimbursement under different federal healthcare programs are not always consistent. Medicare reimbursement rates may also reflect budgetary constraints placed on the Medicare program.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

Ensuring business arrangements with third parties comply with applicable healthcare laws and regulations is a costly endeavor. If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other current or future governmental regulations that apply to us, we may be subject to penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private qui tam actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into government contracts, contractual damages, reputational harm,

administrative burdens, diminished profits and future earnings, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect its ability to operate its business and results of operations.

Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we may obtain regulatory approval. In the United States and in foreign markets, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the extent to which third-party payors provide coverage and establish adequate reimbursement levels for such 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.

Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and reimbursement for these products and related treatments will be available from third-party payors, which decide which therapeutics they will pay for and establish reimbursement levels. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a therapeutic 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.

We cannot be sure that coverage or reimbursement will be available for any product that we commercialize and, if coverage and reimbursement are available, what the level of reimbursement will be. Coverage may also be more limited than the purposes for which the product is approved by the FDA or comparable foreign regulatory authorities. Reimbursement may impact the demand for, or the price of, any product for which we obtain regulatory approval.

Third-party payors are increasingly challenging the price, examining the medical necessity, and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy.

Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with branded drugs and drugs administered under the supervision of a physician. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of its products, in addition to the costs required to obtain FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. Obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our product on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on its investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize any product candidate that it successfully develops.

Different pricing and reimbursement schemes exist in other countries. In the E.U., governments influence the price of biopharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed upon. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to establish their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country. The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care, the increasing influence of health maintenance organizations, and additional legislative changes in the United States has increased, and we expect will continue to increase, the pressure on healthcare pricing. The downward pressure on the rise in healthcare costs in general, particularly prescription medicines, medical devices and surgical procedures and other treatments, 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 products for which we receive regulatory approval, 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. In March 2010, the Affordable Care Act was signed into law, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States. By way of example, the Affordable Care Act increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1%; required collection of rebates for drugs paid by Medicaid managed care organizations; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell certain “branded prescription drugs” to specified federal government programs, implemented a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; expanded eligibility criteria for Medicaid programs; creates a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare Innovation at the Centers for Medicare and Medicaid Services to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the Affordable Care Act or otherwise circumvent some of the requirements for health insurance mandated by the Affordable Care Act. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the Affordable Care Act have passed. For example, in 2017, Congress enacted the Tax Act, which eliminated the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate.” In addition, the 2020 federal spending package permanently eliminates, effective January 1, 2020, the Affordable Care Act-mandated “Cadillac” tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. On December 14, 2018, a Texas U.S. District Court Judge ruled that the individual mandate is a critical and inseverable feature of the Affordable Care Act, and therefore, because it was repealed as part of the Tax Act, the

remaining provisions of the Affordable Care Act are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit ruled that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. On March 2, 2020, the U.S. Supreme Court granted the petitions for writs of certiorari to review the case, although it is unclear when a decision will be made or how the Supreme Court will rule. In addition, there may be other efforts to challenge, repeal or replace the Affordable Care Act. We are continuing to monitor any changes to the Affordable Care Act that, in turn, may potentially impact our business in the future.

Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted, including aggregate reductions of Medicare payments to providers of 2% per fiscal year and reduced payments to several types of Medicare providers, which will remain in effect through 2029 absent additional congressional action. Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted legislation designed, among other things, to bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for pharmaceutical products. For example, at the federal level, the Trump administration released a “Blueprint” to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the other of pocket costs of drug products paid by consumers. Additionally, the Trump administration’s budget proposal for the fiscal year 2020 contains further drug price control measures that could be enacted during the budget process or in future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Although a number of these and other measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. In addition, individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures and, in some cases, 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 therapeutic depends on an in vitro diagnostic, then the FDA generally will require approval or clearance of that diagnostic, known as a companion diagnostic, at the same time that the FDA approves the therapeutic product. In August 2014, the FDA issued final guidance clarifying the requirements that will apply to approval of therapeutic products and in vitro companion diagnostics. According to the guidance, if FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or indication, FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic device is not approved or cleared for that indication. Approval or clearance of the companion diagnostic device will ensure that the device has been adequately evaluated and has adequate performance characteristics in the intended population. The review of in vitro companion diagnostics in conjunction with the review of our therapeutic 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 effectiveness and information about the device and its components regarding, among other things, device design, manufacturing and labeling. Premarket approval applications are subject to an application fee. In addition, premarket approvals for certain devices must generally include the results from extensive preclinical and adequate and well-controlled clinical trials to establish the safety and effectiveness of the device for each indication for which FDA approval is sought. In particular, for a diagnostic, a premarket approval application typically requires data regarding analytical and clinical validation studies. As part of the premarket approval review, the FDA will typically inspect the manufacturer's facilities for compliance with the Quality System Regulation, which imposes elaborate testing, control, documentation and other quality assurance requirements.

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

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

The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The Foreign Corrupt Practices Act also obligates

companies whose securities are listed in the United States to comply with accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Additional Regulation

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines.

We believe that it is in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on its business. We cannot predict, however, how changes in these laws may affect its future operations.

Other Regulations

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

Intellectual Property

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

We have a license to patents and other intellectual property relating to VIP152, VIP217, VIP943, VIP924, VIP236 and our other current product candidates from Bayer on an exclusive, worldwide basis under the Bayer License Agreement. The portfolio as of January 25, 2021 includes 20 issued U.S. patents, 11 pending U.S. patent applications, 263 issued patents in various jurisdictions outside of the United States and approximately 227 pending patent applications in various jurisdictions outside of the United States. The Bayer License Agreement is described more fully below.

Our patent portfolio covering VIP152 consists of issued patents in the U.S., Europe, China, Japan, India, Argentina, Brazil and Mexico, along with issued patents and pending applications in other markets. The issued U.S. patent covering the composition of matter of VIP152 is expected to expire in November 2033, absent any patent term extensions for regulatory delay. With respect to VIP943, we have pending applications in the U.S., Europe, China, Japan, India, Argentina, Brazil and Mexico, and other markets covering the composition of matter of VIP943. Any patent that may issue from our pending patent applications related to VIP943 are expected to expire in December 2037, absent any patent term adjustments or extensions. The patent applications covering the composition of matters of VIP924 and VIP236 have been filed under the Patent Cooperation Treaty, and are each expected to expire in 2039. In addition, our patent portfolio covering VIP217 consists of issued patents in the

U.S., Europe, China, Japan, India, Brazil and Mexico, along with issued patents and pending applications in other markets. The issued U.S. patent covering the composition of matter of VIP217 is expected to expire in 2035, absent any patent term extensions for regulatory delay. With respect to our product candidates and processes 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 and 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 clinical-stage small molecule drug platform, including VIP152 (formerly known as BAY 1251152), a PTEFb inhibitor compound, and (ii) a preclinical stage bioconjugations/next-generation ADC platform, including VIP924 (formerly BAY-924), VIP236, VIP943 (formerly known as BAY-943) next-generation ADC compounds. These platforms currently comprise our entire product candidate pipeline. The Bayer License Agreement became effective upon the closing of the Business Combination and receipt of the Initial Qualified Financing.

Under the Bayer License Agreement, we paid Bayer an upfront license fee of $5.0 million upon the closing of the Business Combination and the receipt of the Initial Qualified Financing. 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 PTEFb licensed product or an ADC licensed product (and which ADC 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 license 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 PTEFb 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.

Our Team

We were incorporated in the State of Delaware in March 2019 and are an early stage start-up company with limited operating history. We exclusively licensed our current pipeline from Bayer under the Bayer License Agreement and intend to bring one or more product candidates through clinical trials and marketing authorization. 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 a break-through blood cancer treatment. Drs. Hamdy and Izumi were instrumental in the clinical development of IMBRUVICA® and CALQUENCE® for the treatment of blood cancers. Drs. Hamdy and Izumi were principal co-founders of Acerta Pharma, the company that developed CALQUENCE® from an early-stage preclinical molecule through clinical trials and full marketing approval. Acerta Pharma was formed to license the preclinical stage molecule and technology that would become CALQUENCE®. Three years after inception, Acerta Pharma was acquired by AstraZeneca plc for $7.0 billion.

Drs. Hamdy and Izumi, our officers, are supported by team of experienced cancer drug developers including Hermes Garban, M.D., our Chief Medical Officer, Hans-Georg Lerchen, Ph.D., our Chief Scientific Officer, co-founder, John C. Byrd, M.D., D. Warren Brown Chair of Leukemia Research at Ohio State University 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.

Our key human capital management objectives are to attract, retain and develop the highest quality talent. To support these objectives, our human resources programs are designed to develop talent to prepare them for critical roles and leadership positions for the future; reward and support employees through competitive pay and benefits; enhance our culture through efforts aimed at making the workplace more engaging and inclusive; and acquire talent and facilitate internal talent mobility to create a high-performing and diverse workforce. As of

February 28, 2021, we had 28 full-time equivalent employees located in the United States. We consider relations with our employees to be good and have never experienced a work stoppage. None of our employees are either represented by a labor union or subject to a collective bargaining agreement.

General 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 Securities and Exchange Commission, or SEC. You may obtain a free copy of these reports in the Investor Relations section of our website, www.invitae.com. All reports that we file with the SEC may be read and copied at the SEC's Public Reference Room at 100 F Street, N.E., Washington, DC, 20549. Information about the operation of the Public Reference Room can be obtained by calling the SEC at 1-800-SEC-0330. All reports that we file are also available at www.sec.gov.

ITEM 1A. Risk Factors.

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

We rely on the Bayer License Agreement to provide rights to the core intellectual property relating to all of our current product candidates, which agreement imposes significant payment and other obligations on us. Any failure by us to perform our obligations under the Bayer License Agreement could give Bayer the right to terminate or seek other remedies under the agreement, and any termination or loss of important rights under the Bayer License Agreement would significantly and adversely affect our ability to develop and commercialize VIP152, VIP943, VIP924, VIP236 and our other current product candidates, raise capital or continue our operations.

We have licensed our current core patents and other intellectual property relating to VIP152, VIP943, VIP924, VIP236 and our other current product candidates from Bayer on an exclusive, worldwide basis under the Bayer License Agreement. See "Business—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 does not become fully effective or thereafter 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 and the receipt of the Initial Qualified Financing. 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 PTEFb 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 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. If we are unable to raise the necessary additional funding, 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 rely on the preclinical and clinical trial data provided by Bayer in assessing the viability of our product candidates, and such preclinical and clinical trial data has not been verified by us or any independent third parties.

We currently license all of our product candidates from Bayer pursuant to the Bayer License Agreement. Our present development involving these product candidates relies upon previous preclinical and clinical trials conducted by Bayer or other third parties over whom we had no control and before we in-licensed the product candidates. We are relying on the results of these preclinical studies and from unaudited clinical trial data from investigator reports that are subject to change. As is typical for Phase 1 studies, such as VIP152, no independent review committee has reviewed the data. Furthermore, if we are unable to replicate the results from Bayer's preclinical or clinical trials in our later preclinical or clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize our product candidates. Although we are not currently aware of any such problems, any problems that emerge with preclinical or clinical development conducted prior to our in-licensing may affect future results or our ability to document prior development and to conduct clinical trials, which could delay, limit or prevent regulatory approval for our product candidates.

Our business, operations and clinical development plans and timelines and supply chain could be adversely affected by the effects of epidemics, including the ongoing COVID-19 pandemic, on the manufacturing, clinical trial and other business activities performed by us or by third parties with whom we conduct business, including our contract manufacturers, contract research organizations, shippers and others.

Our business could be adversely affected by health epidemics wherever we have clinical trial sites or other business operations. In addition, health epidemics could cause significant disruption in the operations of third-party manufacturers, contract research organizations and other third parties upon whom we rely. For example, the COVID-19 pandemic has presented a substantial public health and economic challenge around the world and is affecting employees, patients, communities and business operations, as well as the U.S. economy and financial markets. Many geographic regions have imposed, or in the future may impose, "shelter-in-place" orders, quarantines or similar orders or restrictions to control the spread of COVID-19. Our headquarters is located in Palo Alto, California. At present, we have implemented work-from-home policies for all employees. These measures may negatively impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition.

We are dependent on a worldwide supply chain for products to be used in our clinical trials and, if approved by the regulatory authorities, for commercialization. Quarantines, shelter-in-place and similar government orders, or the expectation that such orders, shutdowns or other restrictions could occur, whether related to COVID-19 or other infectious diseases, could impact personnel at third-party manufacturing facilities in the United States and other countries, or the availability or cost of materials, which could disrupt our supply chain. For example, any

manufacturing supply interruption of any product candidate could adversely affect our ability to conduct ongoing and future clinical trials of such product candidate. In addition, closures of transportation carriers and modal hubs could materially impact our clinical development and any future commercialization timelines.

If our relationships with our suppliers or other vendors are terminated or scaled back as a result of the COVID-19 pandemic or other health 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. Switching or adding additional suppliers or vendors involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new supplier or vendor commences work. As a result, delays could generally occur, which could adversely impact our ability to meet our desired clinical development and any future commercialization timelines. See “Risks Related to Our Dependence on Third Parties.”

In addition, our clinical trials have been and may continue to be affected by the COVID-19 pandemic. Clinical site initiation and patient enrollment may be delayed due to prioritization of hospital resources toward the COVID-19 pandemic or concerns among patients about participating in clinical trials during a pandemic and public health measures imposed by the respective national governments of countries in which the clinical sites are located. Some patients may have difficulty following certain aspects of clinical trial protocols if quarantines 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 to COVID-19 or experience additional restrictions by their institutions, city or state governments could adversely impact our clinical trial operations.

The global pandemic of COVID-19 continues to evolve rapidly. The ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems or the global economy as a whole. However, these effects could have a material impact on our operations, and we will continue to monitor the COVID-19 situation closely.

We are substantially dependent on the success of our lead product candidate, VIP152, which is currently in clinical trials. If we are unable to complete development of, obtain approval for and commercialize VIP152 in a timely manner, our business will be harmed.

Our future success is dependent on our ability to timely complete clinical trials, obtain marketing approval for and successfully commercialize VIP152, our lead product candidate. We believe our highly selective CDK9 inhibitor, VIP152, is differentiated from other CDK9 inhibitor technologies being developed by our competitors. We are investing significant efforts and financial resources in the research and development of VIP152. We are conducting a Phase 1 trial of VIP152 as a monotherapy, in patients with advanced cancers, including non-Hodgkin’s lymphoma. VIP152 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 VIP152, or any other product candidate, before we receive marketing approval from the FDA and comparable foreign regulatory authorities, and we may never receive such marketing approvals.

The success of VIP152 will depend on several factors, including the following:

- the efficacy of VIP152 at selectively targeting CDK9;
- the successful and timely completion of our ongoing clinical trials of VIP152;
- the initiation and successful patient enrollment and completion of additional clinical trials of VIP152 on a timely basis;
- establishing and maintaining relationships with contract research organizations and clinical sites for the clinical development of VIP152 in the United States and internationally;

- the frequency and severity of adverse events in the clinical trials, for example neutropenia is an on-target toxicity of VIP152 and additional drug-related adverse effects are likely to be identified as more patients are treated;
- achieving 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 and manufacturers;
- 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 complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing, distribution and sales efforts of 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 VIP152, which would materially harm our business. If we do not receive marketing approvals for VIP152, we may not be able to continue our operations.

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

VIP152 is a novel PTEFb/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 VIP152 may present novel issues that could cause delays in development or approval. While results from early clinical trials of VIP152 have shown tolerable side effects and a reduction in MCL1 and MYC mRNA, VIP152 may not demonstrate in patients any or all of the pharmacological benefits we believe it may possess. We have not yet succeeded and may never succeed in demonstrating efficacy and safety for VIP152 in pivotal clinical trials or in obtaining marketing approval thereafter. For example, although Bayer has evaluated VIP152 in preclinical studies and in early-stage clinical trials, VIP152 has not yet advanced into a large-scale, pivotal clinical trial for any indication. Positive results from early-stage clinical trials are not necessarily predictive of the results of planned clinical trials of VIP152. If we cannot replicate the positive results from Bayer's Phase 1 clinical trial in our later clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize VIP152. As a result, our focus on exploring PTEFb inhibition may fail to result in the identification of viable additional indications for VIP152. If we are unsuccessful in our development efforts, we may not be able to advance the development of or commercialize VIP152, raise capital, expand our business or continue our operations.

VIP943, VIP924 and VIP236 are part of a novel bioconjugation platform, and their potential therapeutic benefits are unproven. These product candidates are still in the preclinical phase and we do not anticipate beginning clinical trials for any of them until 2022, at the earliest. Furthermore, we may never develop any of the product candidates in our bioconjugation platform. While several bioconjugation and ADC candidates are under development by other companies, there is currently no approved bioconjugation therapy using our proprietary cytotoxin, which we also refer to as our NCE payload, or ADC using KSPi and Cell Trapper™. We may uncover a previously unknown risk associated with KSPi or our NCE payload, our Cell Trapper technology may not be as impermeable as initial testing suggest, our linker technology may not be as effective as initial testing suggests, or other issues that may be more problematic than we currently believe, which may prolong the period of observation required for obtaining, or result in the failure to obtain, regulatory approval or may necessitate

additional preclinical and clinical testing. While results from preclinical trials of VIP943, VIP924 and VIP236 in mouse xenograft models have shown proof-of-concept for each, VIP943, VIP924 and VIP236 may not demonstrate in patients any or all of the pharmacological benefits we believe they may possess. If the KSPi warhead or NCE payload that we use is not safe in certain product candidates, we would be required to abandon or redesign all of our current lead ADC or SMDC product candidates. We have not yet succeeded and may never succeed in demonstrating efficacy and safety of VIP943, VIP924 and VIP236 in pivotal clinical trials or in obtaining marketing approval thereafter. For example, although Bayer has evaluated VIP943, VIP924 and VIP236 in preclinical studies, VIP943, VIP924 and VIP236 have not yet advanced into clinical-stage trials for any indication. Positive results from preclinical trials are not necessarily predictive of the results of planned clinical trials of VIP943, VIP924 and VIP236.

There is currently no CDK9 inhibitor, ADC delivering a KSPi warhead or small molecule drug conjugate delivering a NCE payload that has to date been approved by the FDA, and the development of our product candidates may never lead to a marketable product.

We have not received regulatory approval for any of our product candidates and cannot be certain that our approach will lead to the development of an approvable or marketable product, alone or in combination with other therapies. We may not succeed in demonstrating safety and efficacy of (i) VIP152 in the ongoing Phase 1 clinical trials or in larger-scale clinical trials or (ii) VIP943, VIP924 and VIP236 in preclinical studies, clinical trials or in large-scale clinical trials. Advancing VIP152 as a PTEFb/CDK9 inhibitor, VIP943 and VIP924 as ADCs delivering a KSPi warhead, or VIP236 as a SMDC delivering a NCE payload creates significant challenges for us, including:

- obtaining marketing approval, as the FDA or other regulatory authorities have never approved a CDK9 inhibitor, KSPi, KSPi warhead, or SMDC delivering an NCE payload;
- if any of these product candidates are approved, educating medical personnel regarding the potential efficacy and safety benefits, as well as the challenges, of incorporating such product candidates into existing treatment regimens, including in combination with other treatments for blood and solid cancers; and
- establishing the sales and marketing capabilities upon obtaining any marketing approvals necessary to gain market acceptance.

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

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

The success of 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, including in our pivotal Phase 1 clinical trial of VIP152, 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 the final data being materially different from the preliminary data we previously published. As a result, preliminary data should be viewed with caution until the final data are available. Material adverse changes in the final data compared to preliminary data could significantly harm our business 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 and clinical profile 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; and other potential advantages over alternative treatment methods.

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 or our strategic partners 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 or our strategic partners develop could be significantly diminished and have an adverse material impact on our business.

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

A large number of drug candidates are in development for the treatment of solid tumors, leukemia, B-cell malignancies, lymphomas and myelodysplastic syndrome. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. We believe that a significant number of products are currently under development, and may become commercially available in the future, for the treatment of conditions for which we may attempt to develop product candidates. Several pharmaceutical and biotechnology companies have CDK9 inhibitors, ADCs, SMDCs or other products on the market or in clinical trials which may be competitive to our drugs in hematological and 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. 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 effects, are more convenient, have a broader

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

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

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

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

Our business exposes us to significant product liability risks inherent in the development, testing, manufacturing and marketing of therapeutic treatments. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in an FDA or other regulatory authority investigation of the safety and effectiveness 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 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. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have an adverse effect on our business and financial condition. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics that we or our collaborators may develop.

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

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 foreign and domestic governments as well as private third-party payors. The prices of drugs have been a focus in this effort. Governments and private third-party payors have attempted to control costs by 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.

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

Adverse pricing limitations may hinder our ability to recoup our investment in VIP152, our lead product candidate or any other current or future product candidates, even if such product candidates obtain marketing approval.

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.

Clinical trials are expensive, time consuming, subject to delay 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 complete the development and commercialize 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 or 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 competition for patients from other trials, or if there is limited or no availability of coverage, reimbursement and adequate payment from health maintenance organizations and other third-party payors for the use of agents used in our clinical trials or other reasons;
- unforeseen safety issues;
- uncertain dosing issues that may or may not be related to incompletely explored pharmacokinetic and pharmacodynamics behaviors;
- approval and introduction of new therapies or changes in standards of practice or regulatory guidance that render our clinical trial endpoints or the targeting of our proposed indications less attractive;
- inability to monitor patients adequately during or after treatment or problems with investigator or patient compliance with the trial protocols;
- inability to replicate in large controlled studies safety and efficacy data obtained from a limited number of patients in uncontrolled trials;
- inability or unwillingness of medical investigators to follow our clinical protocols; and
- unavailability of clinical trial supplies.

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

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

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

Certain toxicity and adverse events have been noted in some of the preclinical and clinical trials involving certain of our product candidates. For example, neutropenia was observed in patients receiving VIP152. 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 severely harm our business and reputation.

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

We are making use of biomarkers in certain instances to facilitate our drug development and to optimize our clinical trials. Biomarkers are proteins or other substances whose presence in the blood or tumor cells can serve as an indicator of specific cell processes. We believe that these biomarkers serve a useful purpose in helping us to evaluate whether our product candidates are having their intended effects through their assumed mechanisms, and that they may thus enable us to identify more promising product candidates at an early stage and to 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, then 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 inappropriate product candidates. Moreover, although the FDA has issued for comment a draft guidance document on the potential use of biomarker data in clinical development, such 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 in this connection. Our biomarker data should not be interpreted as evidence of efficacy.

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

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

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

Drs. Ahmed M. Hamdy and Raquel E. Izumi were the principal co-founders of Acerta Pharma BV, the company that developed CALQUENCE® and was eventually acquired by AstraZeneca 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. As such, we make no assurance that Drs. Hamdy and Izumi's past success with Acerta Pharma is indicative of our success or ability to develop and commercialize any of our current or future product candidates.

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

We are in the process of building out and intend to expand and develop new drug candidates. We will be highly dependent on our ability to retain our senior management personnel and recruit additional executive

management and clinical development, scientific, technical and sales and marketing personnel. There is currently intense competition for skilled executives and employees with relevant clinical development, scientific, technical and sales and marketing expertise, and this competition is likely to continue. The loss of the services of any member of our senior management or the inability to attract and retain sufficient clinical development, scientific, technical and managerial personnel may significantly delay or prevent the achievement of drug development and other business objectives and could have a material adverse effect on our business, operating results and financial condition. We also rely on consultants and advisors to assist us in formulating our strategy. 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 us.

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, 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 epidemic, such as the ongoing COVID-19 pandemic, power shortage, telecommunication failure or other natural or man-made accidents or incidents that result in us being unable to fully use our facilities, or the manufacturing facilities of our third party contract manufacturers, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates or the interruption of our business operations for a substantial period of time.

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

Our business and operations would be adversely affected in the event that our computer systems or those of our partners, contract research organizations, contractors, consultants or other third parties we work with were to suffer system failures, cyber-attacks, loss of data or other security incidents.

Despite the implementation of security measures, our computer systems, as well as those of our partners, contract research organizations, 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 cyber-attacks or cyber intrusion, including by computer hackers, foreign governments and cyber-terrorists, have increased significantly and are becoming increasingly difficult to detect. If a failure, accident or security breach were to occur and cause interruptions in our operations, or the operations of our partners or third-party providers, it could result in a misappropriation of confidential information, including our intellectual property or financial information or clinical trial participant personal data, a material disruption or delay in our drug development programs, and/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. Any such breach, loss or compromise of clinical trial participant personal data may also subject us to civil fines and penalties under the privacy laws of the European Union or other countries as well as state and federal privacy laws in the United States.

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

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

We have incurred net losses in each reporting period since our inception, have not generated any revenue from product sales to date and, prior to the Business Combination, have financed our operations principally through loans and other debt. Our losses have resulted principally from expenses incurred in connection with licensing our product candidates from Bayer, raising capital and building our management team and business infrastructure. Our lead product candidate, VIP152, is in Phase 1 clinical trials, and we intend to continue its clinical development in patients with MYC or MCL1-driven hematologic and solid tumors to obtain clinical proof-of-concept in indications with unmet medical needs by the middle of 2022. Our lead ADC product candidates, VIP943 and VIP924, are in preclinical development, and we do not expect them to begin clinical trials until the end of 2022 through the beginning of 2024, respectively. Our SMDC product candidate, VIP236, is in preclinical development, and we do not expect it to begin clinical trials until at least the first half of 2022. Our other product candidates are in the preclinical stage. 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. 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. 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. 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 and/or eliminate one or more of our research and drug development programs or future commercialization efforts.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. We expect our expenses to substantially increase in connection with our ongoing activities, particularly as we initiate and conduct clinical trials of, and seek marketing approval for, VIP152, VIP943, VIP924, VIP236 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, including an upfront license fee upon

consummation of the Business Combination and the receipt of the Initial Qualified Financing 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, including VIP152, VIP943, VIP236 and VIP924, 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.

Upon the completion of the Business Combination, we had approximately $62.2 million in cash and cash equivalents. We intend to use our existing cash and cash equivalents to advance and expand our preclinical and clinical programs, including to fund additional monotherapy and combination clinical studies for our product candidates, and for working capital and other general corporate purposes. Based on current business plans, we believe that our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements through at least the next 12 months. Our estimate as to how long we expect our existing cash and cash equivalents to be able to continue to fund our operating expenses and capital expenditure 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 fewer cash and cash equivalents 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 conditions. We do not have any committed external source of funds. Market volatility resulting from the COVID-19 pandemic 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 research-stage programs, clinical trials or future commercialization efforts.

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

We will be responsible for significant future contingent payments and royalties under the Bayer License Agreement upon the achievement of certain development, regulatory and sales milestone events, some of which may occur prior to commercialization of any of our product candidates. Accordingly, we will 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, including VIP152, VIP943, VIP924 and VIP236. There can be no assurance that we will have the funds necessary to make such payments, or be able to raise such funds when needed, on terms acceptable to us, or at all. As a result, we may be required to delay, limit, reduce or terminate its product development or future commercialization efforts.

We may never achieve or sustain profitability.

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

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

Even if we achieve profitability, we may not be able to sustain profitability in subsequent periods. After we achieve profitability, if ever, we expect to continue to engage in substantial research and development activities and to incur substantial expenses to develop and commercialize additional product candidates. In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our revenues, expenses and profitability.

Our failure to achieve or sustain profitability would depress our market value and could impair our ability to execute our business plan, raise capital, develop additional product candidates or continue our operations. A decline in the value of our company could cause our shareholders to lose all or part of their investment.

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

We have not conducted, managed or completed large-scale or pivotal clinical trials nor managed the regulatory approval process with the FDA or any other regulatory authority with respect to our product candidates. The time required to obtain approvals from the FDA and other regulatory authorities is unpredictable and requires successful completion of extensive clinical trials which typically takes many years, depending upon the type, complexity and novelty of the product candidate. The standards that the FDA and its foreign counterparts use when evaluating clinical trial data can and often does change during drug development, which

makes it difficult to predict with any certainty how they will be applied. We may also encounter unexpected delays or increased costs due to new government regulations, including future legislation or administrative action, or changes in FDA policy during the period of drug development, clinical trials and FDA regulatory review.

Any delay or failure in seeking or obtaining required approvals for a product candidate would have a material and adverse effect on our ability to generate revenue from such product candidate. Furthermore, any regulatory approval to market a product candidate may be subject to significant limitations on the approved uses or indications for which we may market the product candidate or the labeling or other restrictions. In addition, the FDA has the authority to require a Risk Evaluation and Mitigation Strategy as part of approving an NDA or BLA, or after approval, which may impose further requirements or restrictions on the distribution or use of an approved product candidate. These requirements or restrictions might include limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry. These limitations and restrictions may significantly limit the size of the market for a product candidate and affect reimbursement by third-party payors.

We are also subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third party reimbursement. The foreign regulatory approval process varies among countries, and generally includes most if not all of the risks associated with FDA approval as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval. Any delay or failure in obtaining foreign regulatory approval for a product candidate would have a material and adverse effect on our ability to generate revenue from such product candidate in that foreign jurisdiction.

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

If our product candidates are associated with a high and unacceptable severity and prevalence of side effects or unexpected characteristics in preclinical studies or clinical trials when used alone or in combination with other approved products or investigational new drugs, we may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Such results could result in a more restrictive label 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 and may harm our business, financial condition and prospects significantly.

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

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

Further, if any of our product candidates obtains marketing approval, toxicities associated with such product candidates and not seen during clinical testing may also develop after such approval and lead to a requirement to conduct additional clinical safety trials, additional contraindications, warnings and precautions being added to the drug label, significant restrictions on the use of the product or the withdrawal of the product from the market. We cannot predict whether our product candidates will cause toxicities in humans that would preclude or lead to the revocation of regulatory approval based on preclinical studies or early-stage clinical trials.

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

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

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

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

Any regulatory approvals that we may receive for our product candidates will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the product candidate, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a Risk Evaluation and Mitigation Strategy in order to approve our product candidates, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or foreign regulatory authorities approve our product candidates, the

manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, 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 process;
- warning or untitled letters;
- civil and criminal penalties;
- injunctions;
- suspension or withdrawal of regulatory approvals;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- total or partial suspension of production; and
- imposition of restrictions on operations, including costly new manufacturing requirements.

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

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the current U.S. administration may impact our business and industry. Namely, the current U.S. administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these executive actions, including the Executive Orders, will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

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

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

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

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

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. For example, even if the FDA grants accelerated approval of a product candidate, comparable regulatory authorities in foreign jurisdictions, such as the European Medicines Agency, must also approve comparable accelerated approval pathways, such as priority medicines designation, in those countries, and vice versa. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In

many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

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

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

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

The United Kingdom's withdrawal from the European Union may have a negative effect on global economic conditions, financial markets and our business.

The United Kingdom left the European Union on January 31, 2020, an event commonly referred to as "Brexit," and following the "transition period," on December 30, 2020, the European Union, the European Atomic Energy Community and the United Kingdom signed a Trade and Cooperation Agreement.

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

In addition, following the Brexit vote, the European Union moved the European Medicines Agency's headquarters from the United Kingdom to the Netherlands. This transition may cause disruption in the administrative and medical scientific links between the European Medicines Agency and the UK Medicines and

Healthcare products Regulatory Agency, including delays in granting clinical trial authorization or marketing authorization, disruption of import and export of active substance and other components of new drug formulations and disruption of the supply chain for clinical trial product and final authorized formulations. The cumulative effects of the disruption to the regulatory framework may add considerably to the development lead time to marketing authorization and commercialization of products in the European Union and/or the United Kingdom.

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

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

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

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

Our research and development activities could be affected or delayed as a result of possible restrictions on animal testing.

Certain laws and regulations require us to test our product candidates on animals before initiating clinical trials involving humans. Animal testing activities have been the subject of controversy and adverse publicity. Animal rights groups and other organizations and individuals have attempted to stop animal testing activities by pressing for legislation and regulation in these areas and by disrupting these activities through protests and other means. To the extent the activities of these groups are successful, our research and development activities may be interrupted, delayed or become more expensive.

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

We cannot ensure that our compliance controls, policies and procedures will in every instance protect us from acts committed by our employees, agents, contractors or collaborators, including, but not limited to, contract research organizations, electronic data capture companies, data management companies, contract clinical research associates, medical institutions, clinical investigators, contract laboratories and other third parties to assist us in conducting clinical trials and obtaining regulatory approvals for our product candidates, that would violate the laws or regulations of the jurisdictions in which we operate, including, without limitation, healthcare, employment, foreign corrupt practices, environmental, competition, and patient privacy and other privacy laws and regulations. Misconduct by these parties could include intentional failures to comply with FDA or other applicable regulations, provide accurate information to the FDA and comparable regulatory authorities in other jurisdictions, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us.

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

In addition, we are subject to the Foreign Corrupt Practices Act and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate, including the U.K. Bribery Act. The Foreign Corrupt Practices Act generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The Foreign Corrupt Practices Act also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the healthcare providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the Foreign Corrupt Practices Act. Recently, the SEC and Department of Justice have increased their Foreign Corrupt Practices Act enforcement activities with respect to pharmaceutical companies. 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 intend to implement codes of conduct and other policies and controls to mitigate the risk of non-compliance with anti-corruption and anti-bribery laws, it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions stemming from a failure to comply with these laws or regulations. Violations of these laws and regulations could result in, among other things, administrative, civil and criminal fines and

sanctions against us, our officers, or our employees, the closing down of our facilities, requirements to obtain export licenses, exclusion from participation in federal healthcare programs including Medicare and Medicaid, implementation of compliance programs, integrity oversight and reporting obligations, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results and financial condition.

Risks Related to Our Dependence on Third Parties

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

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

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

We do not currently operate our own manufacturing facilities or have our own manufacturing capabilities for clinical or commercial production of our product candidates under development and intend to initially rely on third-party manufactures for any such manufacturing. Third-party manufacturers that have the capabilities, processes and expertise that we need for our product candidates and that can meet our quality standards may be difficult to identify or retain. We do not currently have any agreements in place with any third-party manufacturers for the clinical or commercial production of our product candidates. We anticipate relying on a limited number of third-party manufacturers until such time, if any, as we decide, to expand our operations to include manufacturing capabilities.

If the FDA or comparable foreign regulatory authorities approve any of our product candidates for commercial sale, or if we significantly expand our clinical trials, we will need to manufacture them in larger quantities, and we may not be able to successfully increase the manufacturing capacity for any of our product candidates in a timely or economic manner, or at all. Until such time, if any, that we directly control the manufacturing of our product candidates, we will have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel, and we will be dependent on our third-party manufacturing partners for compliance with current cGMP requirements for the manufacture of our product candidates. If our third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable foreign regulatory authorities, we will not be able to secure or maintain regulatory approval for our product candidates. In addition, if any third-party manufacturer makes improvements in the manufacturing process for our product candidates, we may not own, or may have to share, the intellectual property rights to such innovations.

Any performance failure on the part of manufacturers could delay clinical trials and development or regulatory approval of our product candidates, the commercialization of our product candidate or our ability to sell our commercial products, resulting in additional losses and depriving us of potential product revenues.

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, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way to optimize processes and results. 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 results of planned clinical trials or other future clinical trials conducted with the altered materials. Such changes may also require additional testing, FDA notification or FDA approval. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of product candidates or jeopardize our ability to commence sales and generate revenue.

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

We intend to rely in part on contract research organizations, electronic data capture companies, data management companies, contract clinical research associates, medical institutions, clinical investigators, contract laboratories and other third parties to assist us in conducting clinical trials and obtaining regulatory approvals for our product candidates. In addition, we intend to rely in part on third parties to assist with our preclinical development of product candidates. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if these third parties need to be replaced or if 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.

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

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

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

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

- we may not be able to control the amount and timing of resources that our collaborators may devote to the product candidates;
- our collaborators may experience financial difficulties;
- we may be required to relinquish important rights such as marketing and distribution rights;
- business combinations or significant changes in a collaborator’s business strategy may also adversely affect a collaborator’s willingness or ability to complete its obligations under any arrangement;

- a collaborator could independently move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and
- collaborative arrangements are often terminated or allowed to expire, which would delay development and may increase the cost of developing our product candidates.

Risks Related to Our Intellectual Property

If we fail to comply with our obligations under any license, collaboration or other agreements, 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 VIP152, VIP943, VIP924, VIP236 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 our licensors and us 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 contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidate, which could have a material adverse effect on our business, financial conditions, results of operations and prospects.

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

Our commercial success depends in part on our ability to obtain and maintain patent protection and trade secret protection for VIP152, VIP943, VIP924, VIP236 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 United States and abroad related to our product candidates, proprietary technologies and their uses that are important to our business. We also seek to protect our proprietary position by acquiring or in-licensing relevant issued patents or pending applications from third parties.

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

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

Although we will have licensed patents that cover VIP152 under the Bayer License Agreement, we do not have issued patents covering our other product candidates and we may need additional issued patents covering VIP152. We cannot be certain that the claims in our other U.S. pending patent applications, corresponding international patent applications and patent applications in certain foreign territories, or those of our licensors, will be considered patentable by the USPTO, courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that the claims in our issued patent 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 United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates.

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

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

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

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

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

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

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents or the patents of our licensors may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third party pre-issuance submission of prior art to the USPTO, or become involved in opposition, derivation, revocation, reexamination, post-grant review 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 or 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 and/or is not infringed. If we or any of our potential future collaborators were to initiate legal proceedings against a third party to enforce a patent directed at one of our product candidates, the defendant could counterclaim that our patent or the patent of our licensors is invalid and/or unenforceable in whole or in part. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description, non-enablement, or obviousness-type double patenting. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution.

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

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

affects the validity or enforceability of a claim in our patent and patent applications or the patent and patent applications of our licensors, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim.

If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we may lose at least part, and perhaps all, of the patent protection on such product candidate. In addition, if the breadth or strength of protection provided by our patents and patent applications or the 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.

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

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

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

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

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

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

Derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of derivation proceedings may fail and, even if

successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with such proceedings could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development or manufacturing partnerships that would help us bring our product candidates to market.

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

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

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

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

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

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involve a high degree of technological and legal complexity. Therefore, obtaining and enforcing pharmaceutical patents is costly, time consuming and inherently uncertain. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property and may

increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in our licensor's patents. In addition, Congress or other foreign legislative bodies may pass patent reform legislation that is unfavorable to us.

For example, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty regarding our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the U.S. federal courts, the USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patent and the patents we might obtain or license in the future.

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

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

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

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

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

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

occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

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

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

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

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

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

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

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

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

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

In addition, we rely on the protection of our trade secrets, including unpatented know-how, technology and other proprietary information to maintain our competitive position. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants and advisors, we cannot provide any assurances that all such agreements have been duly executed, and any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

Moreover, third parties may still obtain this information or may come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced, and our competitive position would be harmed. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

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

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

our developmental and commercialization efforts, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

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

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

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

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

A third party may hold intellectual property, including patent rights that are important or necessary to the development of our product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize any current or future product candidates, in which case we would be required to obtain a license from these third parties on commercially reasonable terms. Such a license may not be available, or it may not be available on commercially reasonable terms. Our business would be harmed if we are not able to obtain such a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology.

The risks described elsewhere pertaining to our intellectual property rights also apply to the intellectual property rights that we in-license, including such rights acquired under the Bayer License Agreement, and any failure by us or our licensors to obtain, maintain, defend and enforce these rights could have an adverse effect on our business. In some cases we may not have control over the prosecution, maintenance or enforcement of the patents that we license, and may not have sufficient ability to provide input into the patent prosecution, maintenance and defense process with respect to such patents, and our licensors may fail to take the steps that we believe are necessary or desirable in order to obtain, maintain, defend and enforce the licensed patents.

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

Our commercial success depends in part on avoiding infringement of the patents and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties.

Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our product candidates and products that may be approved in the future, or impair our competitive position. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biopharmaceutical industry, including patent infringement lawsuits, oppositions, reexaminations, inter partes review proceedings and post-grant review proceedings before the USPTO and/or corresponding foreign patent offices. Numerous third party U.S. and foreign issued patents and pending patent applications exist in the fields in which we are developing product candidates. There may be third party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates.

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

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

Although no third party has asserted a claim of patent infringement against us as of the date of this 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 VIP152 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.

It is possible that a third party may assert a claim of patent infringement directed at any of our product candidates. Any patent-related legal action against us claiming damages and seeking to enjoin commercial activities relating to our products, treatment indications, or processes could subject us to significant liability for damages, including treble damages if we were determined to willfully infringe, and require us to obtain a license

to manufacture or market our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. Moreover, even if we or our future strategic partners were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. In addition, we cannot be certain that we could redesign our product candidates, treatment indications, or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing our product candidates, which could harm our business, financial condition and operating results. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing our product candidates and technology.

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

We may 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 may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such 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 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. If we do not prevail in the patent proceedings, the third parties may assert a claim of patent infringement directed at our product candidate.

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

Because our development programs may in the future require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license, or use these third party proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, processes or other third party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third party intellectual property rights is a competitive area, and more established companies may pursue strategies to license or acquire third party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization 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, financial condition, results of operations, 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 make the inventions covered by the issued patents or patent application that we own or license;
- we or our licensors or collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that the pending patent applications we own or license will not lead to issued patents;
- issued patents that we own or license may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may have an adverse effect on our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

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

General Risk Factors

Our stock price is likely to be highly volatile, and you may not be able to sell shares of our common stock at or above the price you paid.

Prior to our initial public offering in March 2020, there was no public market for our common stock, and an active and liquid public market for our stock may not develop or be sustained. In addition, the trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include:

- 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;

- our ability to develop or commercialize products;
- results of the clinical trials and nonclinical studies;
- 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 its current and future product candidates;
- commencement of, or involvement in, litigation involving us;
- changes in our capital structure, such as future issuances of securities or the incurrence of additional debt;
- the volume of shares of our common stock available for public sale;
- any major change in our board of directors or management;
- sales of substantial amounts of our shares of common stock by our executive officers or significant stockholders, or the perception that such sales could occur; and
- general economic and political conditions such as recessions, interest rates, 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. 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 Vincerx because pharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

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

Pursuant to the Voting Agreement, certain of our stockholders, including Dr. Ahmed M. Hamdy, our Chief Executive Officer and Chairman of our board of directors, and Dr. Raquel E. Izumi, our President and Chief Operations Officer, have the right to designate seven of the nine members to our board of directors. As a result, unless and until the parties to the Voting Agreement collectively own less than a majority of our common stock then outstanding or the Voting Agreement terminates, these stockholders could effectively control and direct our board of directors, which in turn may create issues if and to the extent our interests and those of these stockholders diverge. We have not established at this time any procedural mechanisms to address actual or perceived conflicts of interest of such directors and officers and expect that our board of directors, in the exercise of its fiduciary duties, will determine how to address any actual or perceived conflicts of interest on a case-by-case basis. If any corporate opportunity arises and if our directors and officers do not pursue it on our behalf pursuant to the provisions in our Certificate of Incorporation, we may not become aware of, and may potentially lose, a significant business opportunity.

We are a "controlled company" within the meaning of the Nasdaq listing rules and as such are exempt from certain corporate governance requirements.

The listing rules of Nasdaq define a "controlled company" as a company in which more than 50% of the voting power for the election of directors is held by an individual, a group or another company. The Legacy

Holders (including Dr. Ahmed M. Hamdy, our Chief Executive Officer and Chairman of our board of directors, and Dr. Raquel E. Izumi, our President and Chief Operations Officer), the Sponsor, LifeSci Holdings LLC, Rosedale Park, LLC and certain other LSAC stockholders who are parties to the Voting Agreement hold in the aggregate more than 50% of the voting power for our board of directors and by virtue of being parties to the Voting Agreement have the right to elect all of the members of our board of directors. As a result, we are a "controlled company" within the meaning of the Nasdaq listing rules. Therefore, we are not required to comply with certain corporate governance rules that would otherwise apply to us as a listed company on Nasdaq, including the requirement that compensation committee and nominating and corporate governance committee be composed entirely of "independent" directors (as defined by the Nasdaq listing rules). As a "controlled company," our board of directors is not required to include a majority of "independent" directors. Should the interests of the parties to the Voting Agreement differ from those of other stockholders, it is possible that the other stockholders might not be afforded such protections as might exist if our board or committees of our board were required to have a majority, or be composed exclusively, of directors who were independent of the parties to the Voting Agreement or our management. Even though we are a controlled company, we intend to comply with the rules of the SEC and Nasdaq relating to such independence requirements with respect to the composition of our board and the compensation and nominating and corporate governance committees, as applicable to companies which are not "controlled companies."

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

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

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

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

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 financial performance fails 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, it 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 its stock price.

Sales of a substantial number 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.

In accordance with the terms of the Warrant Agreement, outstanding warrants to purchase shares of our common stock became exercisable on March 10, 2021. Additionally, Earnout Shares may be issued in connection with the Merger Agreement, provided that certain conditions are met. To the extent such warrants are exercised

or conditions to receive Earnout Shares are met, additional shares of our common stock will be issued, which will result in dilution to the holders of our common stock and increase the number of shares eligible for resale in the public market. Such shares are eligible for sale in the public market, subject to volume limitations under Rule 144 under the Securities Act of 1933, as amended, or 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 Registration Statement on Form S-1, which was declared effective on February 9, 2021. Sales, or the potential sales, of substantial numbers of shares in the public market could increase the volatility of the market price of our common stock or adversely affect the market price of our common stock.

Sales, or the potential sales, of substantial numbers of shares in the public market by parties to the Lock-up Agreement upon termination of applicable contractual lock-up agreements or by holders of the public warrants upon exercise thereof could increase the volatility of the market price of our common stock or adversely affect the market price of our common stock. Lock-up restrictions pursuant to the Lock-up Agreements terminate on June 23, 2021.

As of December 31, 2020, we had outstanding 13,984,441 shares of common stock (which include 2,744,586 shares of common stock constituting part of the units), 6,563,767 public warrants (which include 2,744,586 public warrants constituting part of the units) and 3,570,000 private warrants outstanding. In addition, we intend to file a registration statement on Form S-8 registering the shares reserved for issuance under our 2020 Incentive Plan, including 3,490,046 shares available for future issuance under our 2020 Incentive Plan, as well as any automatic increases in the number of shares of common stock reserved for future issuance under such plan. The sale or the availability for sale of a large number of our common stock in the public market could cause the price of our common stock to decline.

We do not anticipate paying any cash dividends in the foreseeable future, capital appreciation, if any, would be your sole source of gain.

We currently anticipate that we will retain future earnings for the development, operation and expansion of its business and do not anticipate declaring or paying any cash dividends for the foreseeable future. As a result, capital appreciation, if any, of shares of our common stock would be your sole source of gain on an investment in such shares for the foreseeable future.

We will incur significant increased expenses and administrative burdens as a public company, which could have an adverse effect on our business, financial condition and results of operations.

We face increased legal, accounting, administrative and other costs and expenses as a public company that we did not incur as a private company. The Sarbanes-Oxley Act, including the requirements of Section 404, as well as rules and regulations subsequently implemented by the SEC, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 and the rules and regulations promulgated and to be promulgated thereunder, the PCAOB and the securities exchanges, impose additional reporting and other obligations on public companies. Compliance with public company requirements will increase costs and make certain activities more time-consuming. A number of those requirements require us to carry out activities we have not done previously. In addition, we will incur expenses associated with SEC reporting requirements. Furthermore, 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 rectifying those issues, and the existence of those issues could adversely affect our reputation or investor perceptions of it. It may also be more expensive to obtain director and officer liability insurance. Risks associated with our status as a public company may make it more difficult to attract and retain qualified persons to serve on our board of directors or as executive officers. The additional reporting and other obligations imposed by these rules and regulations will increase legal and financial compliance costs and the costs of related legal, accounting and administrative activities. These increased costs will require us to divert a significant amount of money that could otherwise be used to expand the business and achieve

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 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. We will cease to be an emerging growth company on the date that is the earliest of (1) the last day of the fiscal year in which we have total annual gross revenue of $1.07 billion or more, (2) 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, (3) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years, or (4) 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 ourself of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

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

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

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

Our Certificate of Incorporation requires, to the fullest extent permitted by law, that derivative actions brought in our name, actions against directors, officers and employees for breach of fiduciary duty and other similar actions may be brought 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 issued a decision in Salzburg et al. v. Sciabacucchi, which found that an exclusive forum provision providing for claims under the Securities Act to be brought in federals court is facially valid under Delaware law. It is unclear whether this decision will be appealed, or what the final outcome of this case will be. 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, operating results and financial condition.

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

As of December 31, 2020, each of Dr. Ahmed M. Hamdy, our Chief Executive Officer and Chairman of our board of directors, and Dr. Raquel E. Izumi, our President and Chief Operations Officer, beneficially owns, directly or indirectly, approximately 11.6% of our outstanding common stock, and our directors and executive officers as a group beneficially own approximately 29.9% of our outstanding common stock. As a result, these stockholders will be able to exercise a significant level of control over all matters requiring stockholder approval, including the election of directors, any amendment of our Certificate of Incorporation and approval of significant corporate transactions. In addition, certain of these individuals are party to the Voting Agreement, and have the right to elect all of the members of our board of directors. This control could have the effect of delaying or preventing a change of control or changes in management and will make the approval of certain transactions difficult or impossible without the support of these stockholders.

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

As a public company, we will be required to provide management's attestation on internal controls in the future. The standards required for a public company under Section 404(a) of the Sarbanes-Oxley Act are significantly more stringent than those required of us as a private company. Management may not be able to effectively and timely implement controls and procedures that adequately respond to the 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 securities.

Our management has limited experience in operating a public company.

Our executive officers have limited experience in the management of a publicly traded company. Our management team may not successfully or effectively manage our transition to 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 in future periods.

We may amend the terms of the warrants in a manner that may be adverse to holders with the approval by the holders of a majority of the then outstanding public warrants.

The warrants were issued in registered form under the Warrant Agreement between Continental Stock Transfer & Trust Company, as warrant agent, and us. The Warrant Agreement provides that the terms of the

warrants may be amended without the consent of any holder to cure any ambiguity or correct any defective provision but requires the approval by the holders of a majority of the then outstanding public warrants to make any change that adversely affects the interests of the registered holders. Accordingly, we may amend the terms of the warrants in a manner adverse to a holder if holders of a majority of the then outstanding public warrants approve of such amendment. Although our ability to amend the terms of the warrants with the consent of a majority of the then outstanding public warrants is unlimited, examples of such amendments could be amendments to, among other things, increase the exercise price of the warrants, convert the warrants into stock or cash, shorten the exercise period or decrease the number of warrant shares issuable upon exercise of a warrant.

We may redeem unexpired warrants prior to their exercise at a time that is disadvantageous to the holder, thereby making those warrants worthless.

The private warrants offered hereby will be not redeemable by us so long as they are held by their initial purchasers or their affiliates. However, if the private warrants are sold to you pursuant to this report and you are not an affiliate under the terms of the private warrants, we will have the ability to redeem outstanding warrants at any time after they become exercisable and prior to their expiration, at a price of $0.01 per warrant, provided that the last sales price of common stock equals or exceeds $16.50 per share for any 20 trading days within a 30-trading day period ending on the third business day prior to the date we give notice of redemption. If and when the warrants become redeemable by us, we may exercise our redemption right even if we are unable to register or qualify the underlying securities for sale under all applicable state securities laws. Redemption of the outstanding warrants could force you (i) to exercise your warrants and pay the exercise price therefor at a time when it may be disadvantageous for you to do so, (ii) to sell your warrants at the then-current market price when you might otherwise wish to hold your warrants or (iii) to accept the nominal redemption price which, at the time the outstanding warrants are called for redemption, is likely to be substantially less than the market value of your warrants.

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.

We have identified a material weakness in our internal control over financial reporting that resulted in a restatement of our consolidated financial statements for the year ended December 31, 2020. This material weakness, if not remediated, could again 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.

As described elsewhere in this Amended 10-K, we identified a material weakness in our internal control over financial reporting related to the accounting and reporting for certain of our private warrants. As a result of this material weakness, our management concluded that our internal control over financial reporting was not effective as of December 31, 2020.

To respond to this material weakness, we have devoted, and plan to continue to devote, significant effort and resources to the remediation and improvement of our internal control over financial reporting. The elements of our remediation plan can only be accomplished over time, and we can provide no assurance that these initiatives will ultimately have the intended effects. For a discussion of management's consideration of the material weakness identified with respect to our accounting and reporting for certain of our private warrants see "Note 3—Restatement of Consolidated Financial Statements" to the accompanying consolidated financial statements, and Item 9A, "Controls and Procedures" included in this Amended 10-K.

Any failure to remediate our existing or any future material weaknesses or otherwise 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, results of operations and financial condition.

We can provide no assurance that the measures we have taken and plan to take in the future will remediate the material weakness identified or that any additional material weaknesses or restatements of financial results will not arise in the future due to a failure to implement and maintain adequate internal control over financial reporting or circumvention of these controls. In addition, even if we are successful in strengthening our controls and procedures, in the future these controls and procedures may not be adequate to prevent or identify irregularities or errors or to facilitate the fair presentation of our consolidated financial statements.

ITEM 1B. Unresolved Staff Comments.

None.

ITEM 2. Properties.

Our principal executive offices are located in Palo Alto, California, and our agreement for such space expires in December 2025. 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 for lease to meet 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 units, common stock and public warrants are listed on The Nasdaq Capital Market under the symbols "VINCU," "VINC" and "VINCW," respectively, and were previously listed under the symbols "LSACU," "LSAC" and "LSACW," respectively.

On March 1, 2021, the closing price of our units was $30.90, the closing price of our common stock was $19.24 and the closing price of our public warrants was $3.76 as reported on The Nasdaq Capital Market.

As of March 1, 2021, there were 20 holders of record of our common stock, 1 holder of record of our public warrants, 3 holders of record of our private warrants and 1 holder of record of our units. Because many of our shares of common stock are held by brokers and other nominees on behalf of stockholders, this number is not indicative of the total number of stockholders represented by these stockholders of record.

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

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

The following discussion and analysis has been revised for the effects of the Restatement as discussed in Item 8, Note 3 and 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 upon 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.

On December 23, 2020, LSAC consummated the Business Combination with Legacy Vincera Pharma pursuant to the Merger Agreement. The Business Combination was accounted for as a reverse recapitalization in accordance with U.S. Generally Accepted Accounting Principles, or GAAP. Under this method of accounting, LSAC was treated as the "acquired" company for financial reporting purposes. Except as otherwise provided herein, our financial statement presentation includes (1) the results of Legacy Vincera Pharma as our accounting predecessor for periods prior to the completion of the Business Combination, and (2) the results of the Company for periods after the completion of the Business Combination.

Restatement of Previously Issued Consolidated Financial Statements

This Management's Discussion and Analysis of Financial Condition and Results of Operations has been amended and restated to give effect to the restatement of our consolidated financial statements as of and for the year ended December 31, 2020, as more fully described in the Explanatory Note and in "Note 3—Restatement of Consolidated Financial Statements" to our accompanying consolidated financial statements. For further detail regarding the restatement adjustments, see Explanatory Note, "Note 3—Restatement of Consolidated Financial Statements" and Item 9A, "Controls and Procedures" in this report.

Overview

We are a clinical-stage biopharmaceutical company focused on leveraging our extensive development and oncology expertise to advance new therapies intended to address unmet medical needs for the treatment of cancer. Our current pipeline is entirely derived from the Bayer License Agreement, pursuant to which we have been granted an exclusive, royalty-bearing, worldwide license under certain Bayer patents and know-how to develop, use, manufacture, commercialize, sublicense and distribute (i) a clinical-stage and follow-on small molecule drug program and (ii) a preclinical stage bioconjugation/next-generation antibody-drug conjugate platform. We intend to use these product candidates to treat various cancers in a patient-specific, targeted approach. We believe that these product candidates are differentiated from current programs targeting similar cancer biology, and, if approved, may improve clinical outcomes of patients with cancer.

Despite several decades of advances in targeted therapies, cancer continues to be the second leading cause of death in the United States population per the National Center for Health Statistics. Cancer is not a single disease but rather a constellation of maladies with each requiring a unique approach to vanquish it. Our vision is to address the unmet medical needs of patients with cancer with a diverse pipeline of targeted medicines. The small molecule drug program includes VIP152 (formerly known as BAY 1251152), which is highly selective, clinical-stage PTEFb/CDK9 inhibitor. VIP152 may deliver value-generating data in the second half of 2021. Our ADC platform includes VIP943 (formerly known as BAY-943) and VIP924 (formerly known as BAY-924), which are next-generation ADC compounds addressing known and novel oncology targets that we believe could deliver a greater safety and efficacy profile than current ADC compounds. The bioconjugation program also includes VIP236, an SMDC for solid tumors. In addition to our lead products, we acquired the rights to additional product candidates that are still in the preclinical stage (e.g., VIP217, an oral PTEFb/CDK9 inhibitor).

License Agreement with Bayer

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

Basis of Presentation

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

Components of Results of Operations

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

Revenue

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

Research and Development Expense

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

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

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

multiple projects under development. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We plan to substantially increase our research and development expenses for the foreseeable future as we develop our product candidates and manufacturing processes and conduct discovery and research activities for our preclinical and clinical programs. We cannot determine with certainty the timing of initiation, the duration or the completion costs of current or future preclinical studies and clinical trials of our product candidates due to the inherently unpredictable nature of preclinical and clinical development. Clinical and preclinical development timelines, the probability of success and development costs can differ materially from expectations. We anticipate that we will make determinations as to which product candidates to pursue and how much funding to direct to each product candidate on an ongoing basis in response to the results of ongoing and future preclinical studies and clinical trials, regulatory developments and our ongoing assessments as to each product candidate's commercial potential. We will need to raise substantial additional capital in the future. 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;
- per patient clinical trial costs, including based on the number of doses that patients receive;
- the number of patients who enroll in each clinical trial;
- the number of clinical trials required for approval;
- the number of sites included in the clinical trials;
- the countries in which the clinical trials are conducted;
- the length of time required to enroll eligible patients;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the clinical trials and follow-up;
- the phase of development of the product candidate;
- third party contractors failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- the cost of insurance, including product liability insurance, in connection with clinical trials;
- regulators or institutional review boards requiring that we or our investigators suspend or terminate clinical development for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks; and
- the efficacy and safety profile of our product candidates.

General and Administrative Expenses

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

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our expanded operations and infrastructure, as well as the initiation, continuation and

expansion of our preclinical 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 Year Ended December 31, 2020 and the period from March 1, 2019 (date of inception) through December 31, 2019

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

	For the Year Ended December 31, 2020 (Restated)	For the Period from March 1, 2019 (date of inception) to December 31, 2019	Amount Change
Operating expenses:			
General and administrative	$ 3,598	$ 45	$ 3,553
Research and development—license acquired	5,000	—	5,000
Research and development	2,116	—	2,116
Total operating expenses	10,714	45	10,669
Loss from operations	(10,714)	(45)	(10,669)
Other expense			
Change in fair value of warrant liabilities	(5,136)	—	(5,136)
Financing costs—derivative warrant liabilities	(762)	—	(762)
Interest expense	(8)	—	(8)
Total other expense	(5,906)	—	(5,906)
Net loss	**$ (16,620)**	**$ (45)**	**$ (16,575)**

Research and Development

Research and development expenses increased by $2.1 million for the year ended December 31, 2020 compared to the period from March 1, 2019 to December 31, 2019. The increase was primarily related to an increase of $2.0 million in stock-based compensation from the grant of stock options to purchase 473,000 shares of common stock with a grant date fair value of approximately $5.6 million that was recognized as research and development expense.

Research and Development—license acquired

During the year ended December 31, 2020, we incurred $5.0 million of research and development cost related to the Bayer License Agreement.

General and Administrative

General and administrative expenses increased by approximately $3.5 million for year ended December 31, 2020 compared to the period from March 1, 2019 to December 31, 2019. The increase was primarily related to an increase of $2.3 million in stock-based compensation from the grant of stock options to purchase approximately 575,000 shares of common stock with a grant date fair value of approximately $6.8 million that was recognized as general and administrative expense. The increase also related to the incurrence of $1.1 million of legal and professional expenses primarily related to the Bayer license agreement and the Business Combination, and $0.2 million related to employee's salaries during the year ended December 31, 2020.

Change in Fair Value of Warrant Liabilities

The change in fair value of warrant liabilities was due to the increase in the price of our common stock from $19.00 as of December 23, 2020 to $20.91 as of December 31, 2020.

Subsequent to the Business Combination, we had 3,070,000 private warrants outstanding as of December 31, 2020, which were classified as liability warrants. We had 500,000 amended private warrants outstanding as of December 31, 2020, which were classified as equity warrants.

Financing costs—derivative warrant liabilities

Financing costs of our warrant liabilities reflect an allocation of total financing costs associated with the Business Combination, on the basis of the fair value of the warrant liabilities as compared to the total proceeds received by the Company.

Interest Expense

Interest expense increased by $8,000 for the year ended December 31, 2020 compared to the period from March 1, 2019 to December 31, 2019, due to interest incurred with respect to a related party's outstanding loan. Upon the close of the Business Combination, this loan was repaid in full.

Liquidity and Capital Resources

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 adversely affected. We do not know when, or if, we will generate any revenue from our product candidates, and we do not expect to generate revenue unless and until we obtain regulatory approval of, and commercialize, our product candidates.

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

We will also be responsible for significant payments to Bayer under the Bayer License Agreement. We paid Bayer an upfront license fee of $5.0 million following the closing of the Business Combination and the receipt of the Initial Qualified Financing. In addition, we will also be responsible to Bayer for significant future contingent payments under the Bayer License Agreement upon the achievement of certain development and commercial sales milestones as well as ongoing royalties on net commercial sales. The size and timing of these milestone

payments will vary greatly depending on factors such as the particular licensed product, whether it involves a PTEFb 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. Upon the completion of the Business Combination, we had approximately $62.2 million in cash and cash equivalents. We intend to devote most of the net proceeds from the Business Combination to the preclinical and clinical development of our product candidates, our public company compliance costs and certain of the milestone payments under the Bayer License Agreement. Based on our current business plans, we believe that the anticipated net proceeds from the Business Combination will enable us to fund our operating expenses and capital requirements through at least the next 12 months. Our estimate as to how long we expect the net proceeds from the Business Combination 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 fewer cash and cash equivalents available to us or cause us to consume capital significantly faster than we currently anticipate, and we may need or choose to seek additional funds sooner than planned.

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

- the extent to which we develop, in-license or acquire other product candidates and technologies in our product candidate pipeline;
- the costs and timing of process development and manufacturing scale-up activities associated with our product candidates and other programs as we advance them through preclinical and clinical development;
- the number and development requirements of product candidates that we may pursue;
- the costs, timing and outcome of regulatory review of our product candidates;
- the timing and amount of our milestone payments to Bayer under the Bayer License Agreement;
- our headcount growth and associated costs as 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 studies and clinical trials is a time-consuming, expensive and uncertain process that takes many years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of product candidates that we do not expect to be commercially available in the near term, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the 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.

Adequate additional financing may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our stockholders. 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.

We are continuing to assess the effect that the COVID-19 pandemic may have on our business and operations. The extent to which COVID-19 may impact our business and operations will depend on future developments that are highly uncertain and cannot be predicted with confidence, such as the geographic spread of the disease, the duration of the outbreak, the duration and effect of business disruptions and the short-term effects and ultimate effectiveness of the travel restrictions, quarantines, social distancing requirements and business closures in the United States and other countries to contain and treat the disease. While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, a widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock**.**

Cash Flows

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

	For the Year Ended December 31, 2020 (Restated)	For the Period from March 1, 2019 (date of inception) to December 31, 2019
Net cash used in operating activities	$ (2,279)	$ —
Net cash provided by financing activities	64,071	—

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 research and development and general and administrative activities. As we continue to ramp up hiring and continue and expand clinical trials of, and seek marketing approval for, our product candidates, we expect our cash used in operating activities to increase significantly before we start to generate any material cash flows from our business.

Net cash used in operating activities was approximately $2.3 million for the year ended December 31, 2020 compared to $0 for the period from March 1, 2019 to December 31, 2019. Significant components of our cash used in operating activities consists of approximately $1.0 million in legal and professional services in support of completion of the Bayer License Agreement, formation of our business in preparation for the merger with LSAC and patent costs associated with our portfolio of compounds, as well as an additional $1.0 million in insurance premiums paid upon our transition to a public company. Our net loss during the year ended December 31, 2020 was approximately $16.6 million, which included non-cash expenses of $5.0 million related to the Bayer license, approximately $4.4 million related to stock-based compensation and approximately $5.1 million related to the change in fair value of certain private warrants.

Cash Flows from Financing Activities

Net cash provided by financing activities was $64.1 million for the year ended December 31, 2020 compared to $0 for the period from March 1, 2019 to December 31, 2019. We received approximately $64.1 million in net proceeds from the Business Combination on December 23, 2020. We received $0.3 million from the issuance of shares to certain founders and issuance of a note to a related party. During the year ended December 31, 2020, we made a $0.3 million payment of the note payable to this same related party, which repaid such note in full.

Off-Balance Sheet Arrangements

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

Critical Accounting Policies and Estimates

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

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

Research and Development

Research and development expenses may consist primarily of salaries, benefits and other related costs and expenses, including stock-based compensation, in connection with preclinical development of our product candidates and discovery efforts (including conducting preclinical studies), manufacturing development efforts, preparing for and conducting clinical trials and activities related to regulatory filings for our product candidates. In addition, research and development expenses may include payments to Bayer and other third parties for the

development of our product candidates and the estimated fair value for the issuance of equity for the license rights to products in development (prior to marketing approval). Expenses related to clinical trials may be primarily related to activities at contract research organizations that design, gain approval for and conduct clinical trials on our behalf. Such amounts are then recognized as an expense as the related goods are delivered or the services are performed.

Contingent Milestone Payments

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

The transactions provided for under the Bayer License Agreement will be accounted for as an asset acquisition. Contingent consideration in an asset acquisition is generally recognized when it is probable that a liability has been incurred, and the amount can be reasonably estimated. None of the milestone payments are probable, and no liability 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, or NOL, 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, 2020, there were 10,133,767 warrants to purchase common stock outstanding, consisting of 6,563,767 public warrants (which include 2,744,586 public warrants constituting part of the units) and 3,570,000 private warrants. Each unit consists of one share of common stock and one public warrant exercisable for one-half of one share of common stock.

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

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

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

Since these private warrants meet the definition of a derivative under ASC 815, we recorded these warrants as liabilities on the balance sheet at fair value, with subsequent changes in their respective fair values recognized in the consolidated statement of operations and comprehensive loss at each reporting date. The estimated fair value of the private warrants is determined with Level 3 inputs using Black-Scholes and Monte Carlo simulations. The private warrants were valued as of December 23, 2020 (the Business Combination closing date) and December 31, 2020. See Note 6.

Emerging Growth Company Status

Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can choose not to take

advantage of the extended transition period and comply with the requirements that apply to non-emerging growth companies, and any such election to not take advantage of the extended transition period is irrevocable.

The Company is an “emerging growth company” as defined in Section 2(a) of the Securities Act and has elected to take advantage of the benefits of the extended transition period for new or revised financial accounting standards. The Company expects to remain an emerging growth company at least through the end of the 2021 fiscal year and expects to continue to take advantage of the benefits of the extended transition period, although it 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 cash equivalents consist 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. Currently, we do not possess any cash equivalents, but if we did, the short term nature of these investments would also not be 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 (As Restated).

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm	95
Consolidated Balance Sheets as of December 31, 2020 (Restated) and 2019	96
Consolidated Statements of Operations for the year ended December 31, 2020 (Restated) and for the period from March 1, 2019 (date of inception) through December 31, 2019	97
Consolidated Statements of Stockholders' Equity (Deficit) for the year ended December 31, 2020 (Restated) and for the period from March 1, 2019 (date of inception) through December 31, 2019	98
Consolidated Statements of Cash Flows for the year ended December 31, 2020 (Restated) and for the period from March 1, 2019 (date of inception) through December 31, 2019	99
Notes to Consolidated Financial Statements (Restated)	100

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders 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, 2020 and 2019, the related consolidated statements of operations, changes in stockholders’ equity (deficit), and cash flows for the year ended December 31, 2020 and for the period from March 1, 2019 (date of inception) through December 31, 2019, 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, 2020 and 2019, and the results of its operations and its cash flows for the year ended December 31, 2020 and for the period from March 1, 2019 (date of inception) through December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

Restatement of Financial Statements

As discussed in Note 3 to the consolidated financial statements, the Securities and Exchange Commission issued a public statement entitled Staff Statement on Accounting and Reporting Considerations for Warrants Issued by Special Purpose Acquisition Companies (“SPACs”) (the “Public Statement”) on April 12, 2021, which discusses the accounting for certain warrants as liabilities. The Company previously accounted for its warrants as equity instruments. Management evaluated its warrants against the Public Statement and determined that certain of its private warrants should be accounted for as liabilities. Accordingly, the 2020 consolidated financial statements have been restated to correct the accounting and related disclosure for these warrants.

Basis for Opinion

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

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

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

/s/ WithumSmith+Brown, PC
We have served as the Company’s auditor since 2020
Whippany, New Jersey
May 14, 2021

Vincerx Pharma, Inc.
Consolidated
Balance Sheets

(In thousands, except share and per share amounts)

	December 31, 2020 (Restated)	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 61,792	$ —
Prepaid expenses	1,104	—
Other current assets	214	
Total current assets	63,110	—
Other assets	82	—
Total assets	**$ 63,192**	**$ —**
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities		
Accounts payable	$ 491	$ 35
License payable	5,000	—
Due to related parties	14	9
Common stock warrant liabilities	32,308	—
Total current liabilities	37,813	44
Total liabilities	37,813	44
Commitments and contingencies—Note 6		
Stockholders' equity (deficit)		
Preferred stock, $0.0001 par value; 30,000,000 shares authorized, none issued and outstanding at December 31, 2020 and 2019	—	—
Common stock, $0.0001 par value; 120,000,000 shares authorized as of December 31, 2020 and 2019; 13,984,441 shares and 5,196,000 shares issued and outstanding as of December 31, 2020 and 2019, respectively	1	1
Additional paid-in capital	42,043	1
Subscription receivable	—	(1)
Accumulated deficit	(16,665)	(45)
Total stockholders' equity (deficit)	25,379	(44)
Total liabilities and stockholders' equity (deficit)	**$ 63,192**	**$ —**

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

Vincerx Pharma, Inc.
Consolidated Statements
of Operations

(In thousands, except per share amounts)

	For the Year Ended December 31, 2020 (Restated)	For the Period from March 1, 2019 (date of inception) to December 31, 2019
Operating expenses:		
General and administrative	$ 3,598	$ 45
Research and development—license acquired	5,000	—
Research and development	2,116	—
Total operating expenses	10,714	45
Loss from operations	(10,714)	(45)
Other expense		
Change in fair value of warrant liabilities	(5,136)	—
Financing costs—derivative warrant liabilities	(762)	—
Interest expense	(8)	—
Total other expense	(5,906)	—
Net loss	**$ (16,620)**	**$ (45)**
Net loss per common share, basic and diluted	$ (3.16)	$ (0.01)
Weighted average common shares outstanding, basic and diluted	5,252	4,464

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

Vincerx Pharma, Inc.
Consolidated Statements of Stockholders' Equity (Deficit)

(In thousands)

	Common Stock		Subscription Receivable	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount				
Balance as of March 1, 2019 (date of inception)	—	$ —	$ —	$ —	$ —	$ —
Retroactive application of recapitalization (See Note 4)	(4,134)	—	—	—	—	—
Issuance of founders shares	8,503	1	(1)	—	—	—
Issuance of restricted stock	827	—	—	—	—	—
Stock-based compensation related to restricted stock	—	—	—	1	—	1
Net loss	—	—	—	—	(45)	(45)
Balance as of December 31, 2019	**5,196**	**1**	**(1)**	**1**	**(45)**	**(44)**
Proceeds from reverse acquisition, net of transaction costs and warrant liabilities	8,484	—	—	37,660	—	37,660
Proceeds from Founders	—	—	1	—	—	1
Issuance of restricted stock	304	—	—	—	—	—
Stock-based compensation	—	—	—	4,382	—	4,382
Net loss	—	—	—	—	(16,620)	(16,620)
Balance as of December 31, 2020 (Restated)	**13,984**	**$ 1**	**$ —**	**$ 42,043**	**$ (16,665)**	**$ 25,379**

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

Vincerx Pharma, Inc.
Consolidated Statements
of Cash Flows

(In thousands)

	For the Year Ended December 31, 2020 (Restated)	For the Period from March 1, 2019 (date of inception) to December 31, 2019
Cash flows from operating activities		
Net loss	$ (16,620)	$ (45)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization on debt discount	20	—
Stock-based compensation	4,382	1
Change in fair value of warrant liability	5,136	—
Financing costs—derivative warrant liabilities	762	—
Research and development-acquired license, expensed	5,000	—
Changes in operating assets and liabilities:		
Prepaid and other current assets	(1,318)	—
Other assets	(82)	—
Accounts payable	456	35
Due to related parties	(15)	9
Net cash used in operating activities	(2,279)	—
Cash Flows from Financing Activities:		
Net proceeds from reverse acquisition	64,070	—
Proceeds from Founders	1	—
Proceeds from issuance of notes payable to related parties	300	—
Repayment of notes payable to related parties	(300)	—
Net cash provided by financing activities	64,071	—
Net increase in cash and cash equivalents	61,792	—
Cash and cash equivalents at the beginning of the period	—	—
Cash and cash equivalents at the end of the period	**$ 61,792**	**$ —**
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	$ —	$ —
Cash paid for interest	$ 25	$ —

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

Vincerx Pharma, Inc.
Notes to Consolidated Financial Statements

December 31, 2020

1. Nature of Business

Organization

LifeSci Acquisition Corp. ("LSAC") was initially formed on December 19, 2018 as a Delaware corporation formed for the purpose of effecting a merger, share exchange, asset acquisition, share purchase, reorganization or similar business combination with one or more businesses.

On September 25, 2020, LSAC entered into a Merger Agreement (the "Merger Agreement") with LifeSci Acquisition Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of LSAC ("Merger Sub"), VNRX Corp (f/k/a Vincera Pharma, Inc.), a Delaware corporation ("Vincera Pharma"), and Raquel E. Izumi, as the representative of the stockholders of Vincera Pharma (such stockholders, the "Vincera Pharma stockholders").

Pursuant to the terms of the Merger Agreement, a business combination between LSAC and Vincera Pharma was effected through the merger of Merger Sub with and into Vincera Pharma, with Vincera Pharma surviving as the surviving company and as a wholly-owned subsidiary of LSAC. On December 23, 2020, and in connection with the closing of the business combination (the "Business Combination"), LifeSci Acquisition Corp. changed its name to Vincera Pharma, Inc. In January 2021, Vincera Pharma, Inc. 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/next-generation ADC platform. The Company intends to use these product candidates to treat various cancers in a patient-specific, targeted approach.

During the early months of 2020, COVID-19 emerged and has subsequently spread world-wide. The World Health Organization has declared COVID-19 a pandemic resulting in federal, state and local governments and private entities mediating various restrictions, including travel restrictions, restrictions on public gatherings, stay at home orders, and advisories and quarantining people who may have been exposed to the virus. Management is currently evaluating the impact of the COVID-19 pandemic on its future plans and has concluded that while it is reasonably possible that the virus could have a negative effect on the Company's financial position and results of its operations, the specific impact is not readily determinable as of the date of these consolidated financial statements.

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 subsidiary Vincera Pharma, Inc, also known as VNRX Corp. All intercompany accounts and transactions have been eliminated.

Pursuant to the Merger Agreement, the Business Combination is accounted for as a reverse recapitalization, with no goodwill or other intangible assets recorded, in accordance with GAAP. Under this method of accounting, LSAC is treated as the “acquired” company for financial reporting purposes. Accordingly, for accounting purposes, the Business Combination is treated as the equivalent of Vincera Pharma issuing stock for the net assets of LSAC, accompanied by a recapitalization. As a result, references to the “Company” herein may refer to Vincera Pharma prior to the consummation of the Business Combination. The acquired net assets of LSAC are stated at historical cost, with no goodwill or other intangible assets recorded.

Emerging Growth Company

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

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

Use of Estimates

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

Concentrations of Credit Risk

The Company 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.

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

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

The private warrants are identical to the warrants underlying the units except that (i) each private warrant is exercisable for one share of common stock at an exercise price of $11.50 per share and (ii) such private warrants will be exercisable for cash (even if a registration statement covering the shares of common stock issuable upon exercise of such private warrants is not effective) or on a cashless basis, at the holder's option (except with respect to 500,000 of the private warrants held by Rosedale Park, LLC and 500,000 of the private warrants held by LifeSci Holdings LLC, which were amended to remove the cashless exercise provision), and will not be redeemable by the Company (except with respect to 500,000 of the private warrants held by Rosedale Park, LLC

and 500,000 of the private warrants held by LifeSci Holdings LLC, which were amended to include a redemption provision substantially identical to that of the public warrants; provided, however, that such redemption rights may not be exercised during the first 12 months following the closing of the Business Combination unless the last sales price of the Company's common stock has been equal to or greater than $20.00 per share for any 20 trading days within a 30 trading day period ending on the third business day prior to the date on which notice of redemption is given), in each case so long as they are still held by the initial purchasers or their affiliates. The private warrants purchased by Rosedale Park, LLC will expire on March 5, 2025, provided that once the private warrants are not beneficially owned by Chardan Capital Markets, LLC or any of its related persons anymore, the private warrants may not be exercised five years following the completion of the Company's initial business combination.

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

Since these private warrants meet the definition of a derivative under ASC 815, the Company recorded these warrants as liabilities on the consolidated balance sheet at fair value, with subsequent changes in their respective fair values recognized in the consolidated statement of operations at each reporting date. The estimated fair value of the private warrants is determined with Level 3 inputs using Black-Scholes and Monte Carlo simulations. The private warrants were valued as of December 23, 2020 (the Business Combination closing date) and December 31, 2020. See Note 6.

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 adopted ASU 2018-07, which simplifies the accounting for share-based payments granted to nonemployees for goods and services, on March 1, 2019 (date of inception). 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.

Given the lack of public market for Vincera Pharma's stock prior to the Business Combination, 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 ("NOL") 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, 2020 and 2019, 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 2020 and 2019 since inception.

Comprehensive Income or Loss

Comprehensive loss is equal to net loss as presented in the accompanying consolidated statements of operations, as the Company did not have any other comprehensive income or loss for the periods presented.

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 December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, which is intended to simplify various aspects related to accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in ASC 740 and also clarifies and amends existing guidance to improve consistent application. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020, with early adoption permitted. The Company is currently evaluating the impact of this standard on its consolidated financial statements.

In August 2020, the FASB issued ASU 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, which simplifies accounting for convertible instruments by removing major separation models required under current GAAP. The ASU removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception and it also simplifies the diluted earnings per share calculation in certain areas. The ASU is effective for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2021 and adoption must be as of the beginning of the Company's annual fiscal year. The Company is currently evaluating the impact of this standard on its financial statements and related disclosures.

3. Restatement of Consolidated Financial Statements

On April 12, 2021, the Staff of the SEC issued the "Staff Statement on Accounting and Reporting Considerations for Warrants Issued by Special Purpose Acquisition Companies ("SPACs")" (the "Staff Statement"). The Staff Statement clarified guidance for all SPAC-related companies regarding the accounting and reporting for their warrants that could result in the warrants issued by SPACs being classified as a liability measured at fair value, with non-cash fair value adjustments recorded in the statement of operations for each reporting period.

The Company previously classified its warrants as equity, consistent with market practice among SPACs, including LSAC, the Company's predecessor prior to the Business Combination. The Company reviewed the accounting treatment of its warrants under ASC 815-40, *Derivatives and Hedging—Contracts in Entity's Own Equity*, and evaluated the applicability and potential impact of the Staff Statement on the Company's consolidated financial statements.

Following this review and evaluation, the Company concluded that, in light of the Staff Statement, (i) certain of the private warrants meet the definition of a derivative under ASC 815 and therefore should be accounted for as liabilities measured at fair value, with non-cash fair value adjustments recorded in the operating statement for each reporting period, (ii) warrant offering costs should be expensed and (iii) the Company's audited consolidated financial statements for the year ended December 31, 2020 should no longer be relied upon and should be restated due to the reclassification of these private warrants and related warrant offering costs.

Impact of the Restatement

The impact of the restatement on the Consolidated Balance Sheet, Consolidated Statement of Operations and Consolidated Statement of Cash Flows for the year ended December 31, 2020 is presented below.

	As of December 31, 2020		
	As Previously Reported	Restatement Adjustment	As Restated
	(In thousands, except per share amounts)		
Balance Sheet			
Total assets	$ 63,192	$ —	$ 63,192
Liabilities and stockholders' equity			
Total current liabilities	$ 5,505	$ —	$ 5,505
Common stock warrant liabilities	—	32,308	32,308
Total liabilities	5,505	32,308	37,813
Stockholders' equity			
Preferred stock - $0.0001 par value	—	—	—
Common stock - $0.0001 par value	1	—	1
Additional paid-in-capital	68,453	(26,410)	42,043
Accumulated deficit	(10,767)	(5,898)	(16,665)
Total stockholders' equity	57,687	(32,308)	25,379
Total liabilities and stockholders' equity	$ 63,192	$ —	$ 63,192

	Year Ended December 31, 2020		
	As Previously Reported	Restatement Adjustment	As Restated
	(In thousands, except per share amounts)		
Statement of Operations and Comprehensive Loss			
Loss from operations	$ (10,714)	$ —	$ (10,714)
Other expense:			
Change in fair value of warrant liabilities	—	(5,136)	(5,136)
Financing costs—derivative warrant liabilities		(762)	(762)
Interest expense	(8)	—	(8)
Total other expense	(8)	(5,898)	(5,906)
Net loss	$ (10,722)	$ (5,898)	$ (16,620)
Net loss per common share, basic and diluted	$ (2.04)	—	$ (3.16)
Weighted average common shares outstanding, basic and diluted	5,252	—	5,252

	Year Ended December 31, 2020		
	As Previously Reported	Restatement Adjustment	As Restated
	(In thousands)		
Statement of Cash Flows			
Net loss	$ (10,722)	$ (5,898)	$ (16,620)
Adjustment to reconcile net loss to net cash used in operating activities	8,443	5,898	14,341
Net cash used in operating activities	(2,279)	—	(2,279)
Net cash provided by investing activities	—	—	—
Net cash provided by financing activities	64,071	—	64,071
Net change in cash	$ 61,792	$ —	$ 61,792

The Business Combination is accounted for as a reverse recapitalization in accordance with GAAP. Under this method of accounting, LSAC was treated as the “acquired” company and Vincerx Pharma is treated as the acquirer for financial reporting purposes. Accordingly, for accounting purposes, the Business Combination was treated as the equivalent of Vincera Pharma issuing stock for the net assets of LSAC, accompanied by a recapitalization. The net assets of LSAC were stated at historical cost, with no goodwill or other intangible assets recorded. Additionally, the historical quarterly and annual LSAC financial statements were not restated to reflect this change in accounting described above, as we believe that information is no longer relevant to investors.

4. Business Combination

As discussed in Note 1, on December 23, 2020, the Company consummated the Business Combination, with 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 Vincerx Pharma common stock was canceled, and the Vincera Pharma stockholders received (i) 0.570895 shares of common stock, for each share of Vincera Pharma common stock held by them immediately prior to the effective time of the Business Combination and (ii) certain rights to Earnout Shares after the closing of the Business Combination.

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

The Business Combination is accounted for as a reverse recapitalization in accordance with GAAP. Under this method of accounting, LSAC was treated as the “acquired” company and Vincerx Pharma is treated as the acquirer for financial reporting purposes. Accordingly, for accounting purposes, the Business Combination was treated as the equivalent of Vincera Pharma issuing stock for the net assets of LSAC, accompanied by a recapitalization. The net assets of LSAC were stated at historical cost, with no goodwill or other intangible assets recorded.

The following table reconciles the elements of the Business Combination to the Statement of Cash Flows and the Statement of Stockholders’ Equity (Deficit) for the year ended December 31, 2020 (amounts in thousands):

Cash - LSAC trust	$65,699
Cash - LSAC cash assumed	213
Less: transaction costs and advisory fees	(1,395)
Less: accrued transaction costs and advisory fees	(447)
Net cash contributions from Business Combination	$64,070

The number of shares of common stock issued immediately following the consummation of the Business Combination (amounts in thousands):

LSAC's public stockholders	6,564
LSAC's initial stockholders	1,640
Vincera Pharma stockholders	5,500
Other	280
Total shares of common stock immediately after Business Combination	13,984

5. Bayer License Agreement

On October 7, 2020, 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, 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 small molecule drug platform, including a PTEFb inhibitor compound, and (ii) a preclinical stage bioconjugations/next-generation ADC platform, including next-generation ADC compounds.

Following the closing of the Business Combination, the Company paid Bayer a $5.0 million upfront license fee on January 5, 2021. As of December 31, 2020, the Company recorded a $5.0 million license payable to Bayer.

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.

6. Fair Value Measurement

The Company's financial 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, 2020			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Common stock warrant liabilities (Restated)	$ —	$ —	$ 32,308	$ 32,308
Total fair value	$ —	$ —	$ 32,308	$ 32,308

The Company performs procedures such as comparing prices obtained from independent sources to ensure that appropriate fair values are recorded. Because the transfer of certain private warrants to anyone outside of a small group of individuals constituting the sponsors of LSAC would result in these private warrants having similar terms as the public warrants, management determined that the fair value of each of these private warrants is approximately double that of a public warrant, with a modest adjustment for short-term marketability restrictions. Accordingly, these private warrants are classified as Level 3 financial instruments.

The following table presents changes in Level 3 liabilities measured at fair value for the period ended March 31, 2020. 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—December 23, 2020	$ 27,172
Change in fair value	5,136
Balance—December 23, 2020	$ 32,308

As of December 31, 2020, the fair value of these private warrants was re-measured based on the following assumptions:

	As of December 31, 2020
Exercise Price	$ 11.50
Option term (in years)	5
Volatility	29.4%
Risk-free interest rate	0.4%
Expected dividends	—

7. Notes Payable to Related Party

On August 9, 2020, Vincera Pharma entered into a promissory note with Dr. Raquel E. Izumi, one of its founders (the “Holder”). The principal amount is up to $1.0 million or the amount of outstanding advances made by the Holder to the Company. The Company agreed to pay the Holder a $20,000 origination fee and interest shall accrue at 7%. The maturity date is August 9, 2023.

Between August and December 31, 2020, the Company received $300,000 from the Holder under this note agreement.

On December 23, 2020, the Company repaid $325,000 to the Holder, including the $20,000 origination fee and $5,000 of outstanding interest. As of December 31, 2020, there are no amounts outstanding under this note agreement.

8. 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.

Commitments

On December 23. 2020, the Company entered into a 5-year term lease agreement which commenced on January 1, 2021. The annual rent expense is approximately $847,000.

The Company's future minimum lease payments are as follows as of December 31, 2020 (in thousands):

Year Ended December 31,	
2021	$ 248
2022	807
2023	1,020
2024	1,060
2025	1,102
Total	$4,237

9. 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, 2020, and 2019, there were 13,984,441 shares of common stock (which include 2,744,586 shares of common stock constituting part of the units) and 5,196,000 shares of common stock, respectively, and no shares of preferred stock outstanding.

Founders Shares

Vincera Pharma's three founders (the "Founders") were each issued 1,618,199 shares (2,834,497 shares prior to the effects of the reverse merger) of Vincera Pharma's common stock (the "Founders Shares"), in August 2019. The Founders had not paid the Company for the aggregate par value for their Founder Shares as of December 31, 2019. All amounts owed for the issuance of these Founders Shares were settled in cash in July 2020.

Restricted Shares

Between July and August 2019, Vincera Pharma issued 471,850 shares (826,510 shares prior to the effects of the reverse 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, Vincera Pharma issued an additional 173,552 shares (304,000 shares prior to the effects of the reverse 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 Vincera Pharma's repurchase right for the underlying shares.

As of December 31, 2020, there was approximately $13,000 of unrecognized stock-based compensation related to restricted stock that will be amortized in 3.4 years.

A summary of restricted stock activity for the year ended December 31, 2020 and period ended 2019 is presented below:

	Number of Shares	Weighted Average Grant Date Fair Value per Share
Nonvested at March 1, 2019 (date of inception)	—	$ —
Restricted stock granted	471,850	0.012
Vested	(95,943)	—
Nonvested at December 31, 2019	**375,907**	**0.012**
Restricted stock granted	173,552	0.07
Vested	(188,291)	—
Nonvested at December 31, 2020	**361,168**	**$ 0.016**

Warrants

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

Each public warrant entitles 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 warrants will expire at 5:00 p.m., New York City time, on December 23, 2025 (five years from the closing of the Company's initial business combination).

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

The 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 notes 3 and 6).

10. 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, 2020, the Company had 2,790,824 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 (inyears)	Aggregate Intrinsic Value
Outstanding at January 1, 2020	—	$ —	—	$ —
Options granted	1,048	19.00	10.0	—
Outstanding at December 31, 2020	1,048	$ 19.00	10.0	$ —
Options vested and exercisable at December 31, 2020	349	$ 19.00	10.0	$ —

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 three years.

The Company recognized stock-based compensation of approximately $4.4 million and approximately $1,000 during the year ended December 31, 2020 and for the period from March 1, 2019 (date of inception) through December 31, 2019, respectively.

As of December 31, 2020, the Company had stock-based compensation of approximately $8.1 million related to unvested stock options not yet recognized that are expected to be recognized over an estimated weighted average period of 2.0 years.

The following weighted average assumptions were used as inputs to the Black-Scholes option valuation model in determining the estimated grant-date fair value of the Company's stock options granted during the year ended December 31, 2020:

	December 31, 2020
Exercise price	$ 19.00
Expected term (years)	5.5
Volatility (annual)	75.5%
Risk-free rate	0.4%
Dividend yield (per share)	0%

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

	For the Year ended December 31, 2020
Research and development	$ 2,053
General and administrative	2,329
Total stock-based compensation expense	**$ 4,382**

11. 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, 2020 and for the period from March 1, 2019 (date of inception) through December 31, 2019, respectively (amounts in thousands, except per share number):

	For the Year Ended December 31, 2020 (Restated)	For the Period from March 1, 2019 (date of inception) to December 31, 2019
Numerator:		
Net loss	$ (16,620)	$ (45)
Denominator:		
Weighted average common shares outstanding, basic and diluted	5,252	4,464
Net loss per common share, basic and diluted	$ (3.16)	$ (0.01)

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 Year Ended December 31, 2020	For the Period from March 1, 2019 (date of inception) to December 31, 2019
Options outstanding	1,048	—
Warrants	10,134	—
Total	11,182	—

12. Income Taxes

The Company has no provision for income taxes for the year ended December 31, 2020 and for the period from March 1, 2019 (date of inception) to December 31, 2019. The Company has no current tax expense from losses and no deferred expense from the valuation allowance.

A reconciliation from the U.S. statutory rate of 21% to the effective rate is as follows:

	For the Year Ended December 31, 2020	For the Period from March 1, 2019 (date of inception) to December 31, 2019
Statutory federal income tax rate	21.0%	21.0%
State taxes, net of federal tax benefit	4.5%	7.0%
Change in fair value of warrant liabilities	(6.5%)	0%
Other	(1%)	0%
Change in valuation allowance	(18.0%)	(28.0%)
Income taxes provision (benefit)	0.0%	0.0%

Significant components of the Company's net deferred tax assets as of December 31, 2020 and 2019, are as follows (amounts in thousands):

	As of December 31,	
	2020	2019
Deferred tax assets:		
Amortization	$ 1	$ —
Stock-based compensation	1,226	—
Research and development credit	3	—
Startup costs	—	13
Net operating loss	1,785	—
Total deferred income tax assets	3,015	13
Total deferred income tax liabilities	—	—
Net deferred income tax assets	3,015	13
Valuation allowance	(3,015)	(13)
Deferred tax asset, net of allowance	$ —	$ —

Recognition of deferred tax assets is appropriate when realization of such assets is more likely than not. Based upon the weight of available evidence, which includes the Company's historical operating performance, cumulative net losses, and projected future losses, the Company has provided a full valuation allowance against its deferred tax assets. The Company's valuation allowance increased by $3.0 million for the year ended December 31, 2020.

At December 31, 2020, the Company had federal and state net operating loss carryforwards of approximately $6.4 million. The federal net operating loss carryforwards can be carried forward indefinitely, with certain limitations. For the year ended December 31, 2020 and for the period from March 1, 2019 (date of inception) to December 31, 2019, the Company has used a 100% apportionment factor for California net operating losses. A portion of the state net operating loss carryforwards will expire beginning in 2039, if not utilized.

As of December 31, 2020, the Company also has Federal and California research and development credits of $1,820 and $1,365, respectively. The federal tax credit carryforwards will expire beginning in 2039, if not utilized. The state tax credit carryforwards do not expire.

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, 2020. 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. The Company had not identified any material unrecognized tax benefit in accordance with ASC 740-10.

The federal and state income tax returns are open under the statute of limitations subject to tax examinations for the tax years ended December 31, 2020 and 2019. To the extent the Company has tax attribute carryforwards, the tax year in which the attribute was generated may still be adjusted upon examination by the IRS or state tax authorities to the extent utilized in a future period.

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

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

13. Subsequent Events

As mentioned in Note 8 above, the Company’s office lease agreement became effective on January 1, 2021. Upon adoption of ASU 2016-02, Leases (Topic 842) and upon occupancy, the Company expects to record right-of-use assets and lease liabilities of approximately $3.3 million, which represents the discounted cash flows of this operating lease as of the commencement date.

On April 5, 2021, the Company announced that it would redeem all of its outstanding public warrants to purchase shares of the Company’s common stock that were issued under the Warrant Agreement, dated March 5, 2020, by and between the Company and Continental Stock Transfer & Trust Company, as warrant agent, as part of the units sold in the Company’s initial public offering, that remained outstanding and unexercised on May 5, 2021, the redemption date, at a redemption price of $0.01 per public warrant. In addition to the $8.2 million of cash received on April 1, 2021 from the exercise of public and private placement warrants in March 2021, prior to the redemption notice, the Company also received additional proceeds of approximately $32.5 million from the exercise of additional public and private warrants during the redemption period. Pursuant to the redemption, a total of 40,491 public warrants were unexercised and redeemed by the Company at the redemption price of $0.01 per public warrant. As of the close of business on May 7, 2021, there were 17,521,075 shares of the Company’s common stock outstanding.

Other than the two items noted here, there have been no other subsequent events identified by management.

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 (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.

Our management, with the participation of our Chief Executive Officer (our principal executive officer) and our Chief Financial Officer (our principal financial officer), has evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2020, the end of the period covered by this Annual Report on Form 10-K. At the time our Annual Report on Form 10-K for the year ended December 31, 2020 was filed on March 22, 2021, our Chief Executive Officer and our Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level. Solely as a result of the material weakness in our internal control over financial reporting discussed below and elsewhere in this Amended 10-K, our Chief Executive Officer and Chief Financial Officer have concluded that, as of December 31, 2020, our disclosure controls and procedures were not effective at the reasonable assurance level.

Management’s Annual Report on Internal Control over Financial Reporting

This annual report does not include a report of management’s assessment regarding internal control over financial reporting or an attestation report of our registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

Changes in Internal Control over Financial Reporting

As discussed elsewhere in this Amended 10-K, we identified a material weakness in our control over the accounting for complex financial instruments. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that a reasonable possibility exists that a material misstatement of our annual or interim financial statements could not be prevented or detected on a timely basis.

During the most recently completed fiscal quarter, there has been no change in our internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting, as the circumstances that led to the restatement of our financial statements described in this Annual Report on Form 10-K had not yet been identified. To remediate the material weakness in our internal control over financial reporting discussed below and elsewhere in this report, which was identified following the most recently completed fiscal quarter, we have devoted, and plan to continue to devote, significant effort and resources to the improvement of our internal control over financial reporting. While we have processes to identify and appropriately apply applicable accounting requirements, we plan to enhance these processes to better evaluate our research and understanding of the nuances of the complex accounting standards that apply to our consolidated financial statements. Our plans at this time include providing enhanced access to accounting literature, research materials and documents and increased communication among our personnel and third-party

professionals with whom we consult regarding complex accounting applications. The elements of our remediation plan can only be accomplished over time, and we can provide no assurance that these initiatives will ultimately have the intended effects.

ITEM 9B. Other Information.

None.

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, 2020 in connection with the solicitation of proxies for our 2021 Annual Meeting of Stockholders, or the Proxy Statement. Certain information required by this item concerning executive officers is set forth in Part I of this Report under the caption “Information About our 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 http://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: Chief Financial 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.

Our Board of Directors has appointed an Audit Committee, comprised of Laura I. Bushnell, John H. Lee and Christopher P. Lowe. The Board of Directors has determined that Christopher P. Lowe qualifies as an Audit Committee Financial Expert under the definition outlined by the Securities and Exchange Commission. In addition, each of the members of the Audit Committee qualifies as an “independent director” under the current rules of the New York Stock Exchange and Securities and Exchange Commission rules and regulations.

ITEM 11. Executive Compensation.

The information required by this item is incorporated by reference from the information under the captions “Election of Directors-Director Compensation” 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 caption “Election of Directors-Certain Relationships and Related Transactions,” “Election of Directors-Corporate Governance” and “Director Independence” 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 the 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 hereof.

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 compensating 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).

Exhibit No.	Description
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K filed on January 11, 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	Voting and Support Agreement by and among the Company and certain stockholders of the Company, dated December 23, 2020 (incorporated by reference to Exhibit 4.5 to the Current Report on Form 8-K filed on December 30, 2020).
4.6	Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934 (incorporated by reference to Exhibit 4.6 to the Annual Report on Form 10-K for the year ended December 31, 2020).
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 Hermes Garban, dated December 23, 2020 (incorporated by reference to Exhibit 10.7 to the Annual Report on Form 10-K for the year ended December 31, 2020).
10.8#	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).
10.9*	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).

Exhibit No.	Description
10.10	Promissory Note by and between the Company and Dr. Raquel E. Izumi, dated August 9, 2020 (incorporated by reference to Exhibit 10.8 to the Current Report on Form 8-K filed on December 30, 2020).
10.11	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).
10.12	Form of Lock-up Agreement by and between the Company and certain stockholders of the Company, dated December 23, 2020 (incorporated by reference to Exhibit 10.10 to the Current Report on Form 8-K filed on December 30, 2020).
10.13	Letter Agreements, dated March 5, 2020, among LifeSci Acquisition Corp. and LifeSci Acquisition Corp.'s officers, directors and initial stockholders (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q filed on November 10, 2020).
10.14	Stock Escrow Agreement, dated March 5, 2020, among LifeSci Acquisition Corp., Continental Stock Transfer & Trust Company and LifeSci Acquisition Corp.'s initial stockholders (incorporated by reference to Exhibit 10.3 to the Quarterly Report on Form 10-Q filed on November 10, 2020).
21.1	Subsidiaries of the Company (incorporated by reference to Exhibit 21.1 to the Current Report on Form 8-K filed on December 30, 2020).
23.1	Consent of independent registered public accounting firm.
24.1	Power of Attorney (incorporated by reference to Exhibit 24.1 to the Annual Report on Form 10-K for the year ended December 31, 2020).
31.1	Principal Executive Officer's Certifications Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Principal Financial Officer's Certifications Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1†	Certification Pursuant to 18 U.S.C. § 1350 (Section 906 of Sarbanes-Oxley Act of 2002).
32.2†	Certification Pursuant to 18 U.S.C. § 1350 (Section 906 of Sarbanes-Oxley Act of 2002).
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase 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 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 Amended 10-K and will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, or 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
Dr. Ahmed M. Hamdy
Chief Executive Officer

Date: May 14, 2021

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-1 (Registration No. 333-252589) of our report dated May 14, 2021, relating to the consolidated financial statements of Vincerx Pharma, Inc., which appear in this Form 10-K, as amended.

/s/ WithumSmith+Brown, PC

Whippany, New Jersey
May 14, 2021

Exhibit 31.1

Certification of Principal Executive Officer Pursuant to Exchange Act Rule 13a-14(a)/15d-14(a) as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Dr. Ahmed M. Hamdy, certify that:

1. I have reviewed this Amendment No. 1 to the Annual Report on Form 10-K of Vincerx Pharma, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 14, 2021

/s/ Dr. Ahmed M. Hamdy
Dr. Ahmed M. Hamdy
Chief Executive Officer (Principal Executive Officer)

Exhibit 31.2

Certification of Principal Financial Officer Pursuant to Exchange Act Rule 13a-14(a)/15d-14(a) as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Alexander A. Seelenberger, certify that:

1. I have reviewed this Amendment No. 1 to the Annual Report on Form 10-K of Vincerx Pharma, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 14, 2021

/s/ Alexander A. Seelenberger
Alexander A. Seelenberger
Chief Financial Officer (Principal Financial Officer)

Exhibit 32.1

Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, I, Dr. Ahmed M. Hamdy, the Chief Executive Officer (Principal Executive Officer) of Vincera Pharma, Inc. (the "Company"), hereby certify, that, to my knowledge:

1. The Amendment No. 1 to the Annual Report on Form 10-K for the year ended December 31, 2020 (the "Report") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 14, 2021

/s/ Dr. Ahmed M. Hamdy
Dr. Ahmed M. Hamdy
Chief Executive Officer (Principal Executive Officer)

This certification shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Exhibit 32.2

Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, I, Alexander A. Seelenberger, the Chief Financial Officer (Principal Financial Officer) of Vincera Pharma, Inc. (the "Company"), hereby certify, that, to my knowledge:

1. The Amendment No. 1 to the Annual Report on Form 10-K for the year ended December 31, 2020 (the "Report") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 14, 2021

/s/ Alexander A. Seelenberger
Alexander A. Seelenberger
Chief Financial Officer (Principal Financial Officer)

This certification shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.