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

# FORM 10-Q

**(Mark One)**

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

**For the quarterly period ended June 30, 2022**

**OR**

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

**For the transition period from _____ to _____**

**Commission file number 001-39244**

# Vincerx Pharma, Inc.
**(Exact name of Registrant as Specified in Its Charter)**

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

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

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

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|---|---|
| **Common Stock, $0.0001 par value per share** | **VINC** | **The Nasdaq Stock Market LLC** |

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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of July 31, 2022, there were 21,189,769 shares of the registrant’s common stock outstanding.

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**Forward-Looking Statements**

This report contains forward-looking statements that involve risks and uncertainties. These statements relate to future periods, future events or our future operating or financial plans or performance. When used in this report, the words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intends,” “forecast,” “goal,” “may,” “might,” “on-target,” “plan,” “possible,” “potential,” “predict,” “project,” “should,” “seeks,” “suggests,” “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 terms of the Bayer License Agreement;
- developments and projections relating to our competitors and industry;
- our expectations regarding our ability to obtain, develop and maintain intellectual property protection and not infringe on the rights of others;
- our ability to retain key scientific or management personnel;
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act;
- our future capital requirements and sufficiency of available cash, including our expected cash runway, and the timing of those requirements and sources and uses of cash;
- our ability to obtain funding for our operations;
- the impact of our strategic prioritization and cost reduction measures;
- the outcome of any known and unknown litigation and regulatory proceedings;
- our business, plans and opportunities; and
- changes in applicable laws or regulations.

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

- risks associated with preclinical or clinical development and trials, including those conducted prior to our in-licensing;
- risks related to the rollout of our business and the timing of expected business milestones;
- changes in the assumptions underlying our expectations regarding our future business or business model;
- our ability to develop, manufacture and commercialize product candidates;
- general economic, financial, legal, political and business conditions and changes in domestic and foreign markets;
- changes in applicable laws or regulations;
- the impact of natural disasters, including climate change, and the impact of health 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;
- risks related to our plans and assumptions regarding the availability, use and sufficiency of our cash resources;
- our ability to raise capital;
- our ability to successfully implement our workforce and cost reductions and the impact of such reductions;
- 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 Securities and Exchange Commission (the "SEC"), we expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based. You should, however, review additional disclosures we make in our definitive proxy statement for the 2022 Annual Meeting of Stockholders, Annual Report on Form 10-K for the year ended December 31, 2021, 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 LifeSci Acquisition Corp., our predecessor company prior to the consummation of the Business Combination (as defined below). Additional terms frequently used in this report include the following:

- "ADC" means antibody-drug conjugate.
- "Affordable Care Act" means the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act.
- "AML" means acute myeloid leukemia.
- "ANDA" means an abbreviated new drug application.
- "Bayer License Agreement" means that certain License Agreement, dated October 7, 2020, by and among Legacy Vincera Pharma, Bayer Aktiengesellschaft and Bayer Intellectual Property GmbH.
- "BLA" means a biologics license application.
- "BPCIA" means the Biologics Price Competition and Innovation Act of 2009.
- "Business Combination" means the Merger and the other transactions described in the Merger Agreement.
- "BTKi" means Bruton tyrosine kinase inhibitor.
- "Bylaws" means our amended and restated bylaws.
- "Certificate of Incorporation" means our second amended and restated certificate of incorporation, as amended.
- "cGMP" means current Good Manufacturing Practice.
- "CLL" means chronic lymphocytic leukemia.
- "common stock" means our common stock, $0.0001 par value per share.
- "double-hit DLBCL" means diffuse large B-cell lymphoma that is characterized by translocations of MYC and BCL-2.
- "Earnout Shares" means certain rights to common stock after the closing of the Business Combination that Legacy Holders may be entitled to receive pursuant to the Merger Agreement.
- "Exchange Act" means the Securities Exchange Act of 1934, as amended.
- "FDA" means the U.S. Food and Drug Administration.
- "IND" means an investigational new drug application.
- "JOBS Act" means the Jumpstart Our Business Startups Act of 2012.
- "KSPi" means kinesin spindle protein inhibitor.
- "Legacy Holders" means the stockholders of Legacy Vincera Pharma immediately prior to the Business Combination.
- "Legacy Vincera Pharma" means Vincera Pharma, Inc. prior to the consummation of the Business Combination, which changed its name to VNRX Corp. following the Business Combination.

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

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

**Summary Risk Factors**

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

- We rely on the Bayer License Agreement to provide rights to the core intellectual property relating to all of our current product candidates, which agreement imposes significant payment and other obligations on us. Any failure by us to perform our obligations under the Bayer License Agreement could give Bayer AG ("Bayer") the right to terminate or seek other remedies under the agreement, and any termination or loss of important rights under the Bayer License Agreement would significantly and adversely affect our ability to develop and commercialize enitociclib (formerly VIP152), VIP943, VIP924, VIP236 and our other current product candidates, raise capital or continue our operations.
- Our preclinical development, clinical trials, manufacturing, supply chains and other operations and business activities, and the operations and business activities of third parties with whom we conduct business, including our contract manufacturers, contract research organizations, shippers, clinical trial sites and others, have been, and continue to be, adversely affected by the effects of epidemics, including the ongoing COVID-19 pandemic.
- We are dependent in large part on the success of our lead product candidate, enitociclib, which is currently in clinical trials. If we are unable to complete development of, successfully complete clinical trials, obtain approval for and commercialize enitociclib in a timely manner, our business will be harmed.
- We are at an early stage in development efforts for our product candidates, and we may not be able to successfully develop, manufacture, complete clinical trials and commercialize our product candidates on a timely basis or at all.
- There is currently no CDK9 inhibitor, ADC delivering a KSPi warhead or small molecule drug conjugate delivering an optimized CPT 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 rely in part 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 long-term prospects depend in part upon discovering, developing, manufacturing and commercializing additional product candidates, which may fail in development or clinical trials, 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 enrollment and other delays and may be required to continue beyond our available funding, and we cannot be certain that we will be able to raise sufficient funds to successfully complete the development, clinical trials and commercialization of any of our product candidates currently in preclinical and clinical development, should they succeed.
- 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 recently implemented certain workforce and cost reduction measures in connection with our strategic plan, and there can be no assurance that we will be able to successfully implement these workforce and cost reductions or that such measures will not adversely affect our business.
- 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 product candidates.
- We may be unable to obtain U.S. or foreign regulatory approvals and, as a result, may be unable to commercialize our product candidates.
- Our current or future product candidates may cause adverse events, toxicities or other undesirable side effects when used alone or in combination with other approved products or investigational new drugs that may result in a safety profile that could inhibit regulatory approval, prevent market acceptance, limit their commercial potential or result in significant negative consequences.

## PART I

**ITEM 1. Financial Statements.**

### VINCERX PHARMA, INC.
### CONDENSED CONSOLIDATED BALANCE SHEETS

*(In thousands, except share and per share amounts)*

| | June 30, 2022 (Unaudited) | December 31, 2021 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash | $ 80,857 | $ 111,459 |
| Restricted cash | 63 | 105 |
| Prepaid expenses | 847 | 182 |
| Other current assets | 619 | 95 |
| Total current assets | 82,386 | 111,841 |
| Right-of-use assets | 3,514 | 3,949 |
| Property, plant and equipment, net | 202 | 233 |
| Other assets | 1,642 | 1,653 |
| **Total assets** | **$ 87,744** | **$ 117,676** |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities | | |
| Accounts payable | $ 5,118 | $ 2,019 |
| Accrued expenses | 4,331 | 4,715 |
| Lease liability | 968 | 738 |
| Common stock warrant liabilities | 34 | 6,447 |
| Total current liabilities | 10,451 | 13,919 |
| Lease liability, net of current portion | 2,930 | 3,436 |
| Total liabilities | 13,381 | 17,355 |
| **Commitments and contingencies - Note 6** | | |
| **Stockholders' equity** | | |
| Preferred stock, $0.0001 par value; 30,000,000 shares authorized, none issued and outstanding as of June 30, 2022 and December 31, 2021 | — | — |
| Common stock, $0.0001 par value; 120,000,000 shares authorized, 21,189,769 shares and 21,057,560 shares issued and outstanding as of June 30, 2022 and December 31, 2021, respectively | 2 | 2 |
| Additional paid-in capital | 165,173 | 156,311 |
| Accumulated other comprehensive income (loss) | 4 | (21) |
| Accumulated deficit | (90,816) | (55,971) |
| Total stockholders' equity | 74,363 | 100,321 |
| **Total liabilities and stockholders' equity** | **$ 87,744** | **$ 117,676** |

The accompanying notes are an integral part of the unaudited condensed consolidated financial statements.

**VINCERX PHARMA, INC.**
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**

**(Unaudited)**
*(In thousands, except per share amounts)*

| | For the three months ended June 30, | | For the six months ended June 30, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| **Operating expenses:** | | | | |
| General and administrative | $ 4,722 | $ 6,695 | $ 10,378 | $ 11,486 |
| Research and development | 13,742 | 10,698 | 29,713 | 15,532 |
| Restructuring | 1,159 | — | 1,159 | — |
| Total operating expenses | 19,623 | 17,393 | 41,250 | 27,018 |
| **Loss from operations** | (19,623) | (17,393) | (41,250) | (27,018) |
| **Other income (expense)** | | | | |
| Change in fair value of warrant liabilities | 1,202 | 15,359 | 6,413 | 18,708 |
| Other expense | — | — | (8) | — |
| Total other income (expense) | 1,202 | 15,359 | 6,405 | 18,708 |
| **Net loss** | **(18,421)** | **(2,034)** | **(34,845)** | **(8,310)** |
| Other comprehensive income: | | | | |
| Net foreign currency translation gain | 10 | — | 25 | — |
| **Comprehensive loss** | **$ (18,411)** | **$ (2,034)** | **$ (34,820)** | **$ (8,310)** |
| Net loss per common share, basic and diluted | $ (0.88) | $ (0.12) | $ (1.66) | $ (0.55) |
| Weighted average common shares outstanding, basic and diluted | 20,995 | 16,350 | 20,946 | 15,050 |

The accompanying notes are an integral part of the unaudited condensed consolidated financial statements.

**VINCERX PHARMA, INC.**
**CONDENSED CONSOLIDATED STATEMENTS OF CHANGES**
**IN STOCKHOLDERS' EQUITY**
**(Unaudited)**
**(*in thousands*)**

| | For the Three Months Ended June 30, 2022 | | | | | |
|---|---|---|---|---|---|---|
| | Common Stock | | Additional Paid-in Capital | Accumulated Other Comprehensive Income (Loss) | Accumulated Deficit | Total Stockholders' Equity |
| | Shares | Amount | | | | |
| **Balance as of April 1, 2022** | **21,057** | **$ 2** | **$ 161,569** | **$ (6)** | **$ (72,395)** | **$ 89,170** |
| Issuance of common stock from employee stock plans | 132 | — | 242 | — | — | 242 |
| Stock-based compensation | — | — | 3,362 | — | — | 3,362 |
| Cumulative translation adjustment | — | — | — | 10 | — | 10 |
| Net loss | — | — | | — | (18,421) | (18,421) |
| **Balance as of June 30, 2022** | **21,189** | **$ 2** | **$ 165,173** | **$ 4** | **$ (90,816)** | **$ 74,363** |

| | For the Six Months Ended June 30, 2022 | | | | | |
|---|---|---|---|---|---|---|
| | Common Stock | | Additional Paid-in Capital | Accumulated Other Comprehensive Income (Loss) | Accumulated Deficit | Total Stockholders' Equity |
| | Shares | Amount | | | | |
| **Balance as of January 1, 2022** | **21,057** | **$ 2** | **$ 156,311** | **$ (21)** | **$ (55,971)** | **$ 100,321** |
| Issuance of common stock from employee stock plans | 132 | — | 242 | — | — | 242 |
| Stock-based compensation | — | — | 8,620 | — | — | 8,620 |
| Cumulative translation adjustment | — | — | — | 25 | — | 25 |
| Net loss | — | — | — | — | (34,845) | (34,845) |
| **Balance as of June 30, 2022** | **21,189** | **$ 2** | **$ 165,173** | **$ 4** | **$ (90,816)** | **$ 74,363** |

| | For the Three Months Ended June 30, 2021 | | | | | |
|---|---|---|---|---|---|---|
| | Common Stock | | Subscription Receivable | Additional Paid-in Capital | Accumulated Deficit | Total Stockholders' Equity |
| | Shares | Amount | | | | |
| **Balance as of April 1, 2021** | **14,696** | **$ 1** | **$ (8,182)** | **$ 56,675** | **$ (22,941)** | **$ 25,553** |
| Issuance of common stock from warrant exercises | 2,825 | — | 8,182 | 32,489 | — | 40,671 |
| Reclassification of warrant liabilities to equity due to warrant exercises for cash | — | — | — | 768 | — | 768 |
| Stock-based compensation | — | — | | 6,637 | — | 6,637 |
| Net loss | — | — | | — | (2,034) | (2,034) |
| **Balance as of June 30, 2021** | **17,521** | **$ 1** | **$ —** | **$ 96,569** | **$ (24,975)** | **$ 71,595** |

| | For the Six Months Ended June 30, 2021 | | | | |
|---|---|---|---|---|---|
| | Common Stock | | Additional Paid-in Capital | Accumulated Deficit | Total Stockholders' Equity |
| | Shares | Amount | | | |
| **Balance as of January 1, 2021** | **13,984** | **$ 1** | **$ 42,043** | **$ (16,665)** | **$ 25,379** |
| Issuance of common stock from warrant exercises | 3,537 | — | 40,671 | — | 40,671 |
| Reclassification of warrant liabilities to equity due to warrant exercises for cash | — | — | 2,503 | — | 2,503 |
| Stock-based compensation | — | — | 11,352 | — | 11,352 |
| Net loss | — | — | — | (8,310) | (8,310) |
| **Balance as of June 30, 2021** | **17,521** | **$ 1** | **$ 96,569** | **$ (24,975)** | **$ 71,595** |

The accompanying notes are an integral part of the unaudited condensed consolidated financial statements.

**VINCERX PHARMA, INC.**
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**
**(Unaudited)**
**(*in thousands*)**

| | For the six months ended June 30, | |
|---|---|---|
| | **2022** | **2021** |
| **Cash flows from operating activities** | | |
| Net loss | $ (34,845) | $ (8,310) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation | 27 | — |
| Stock-based compensation | 8,620 | 11,352 |
| Amortization of right-of-use assets | 435 | (51) |
| Change in fair value of warrant liabilities | (6,413) | (18,708) |
| Changes in operating assets and liabilities: | | |
| Prepaid and other current assets | (1,189) | 436 |
| Other assets | 11 | (105) |
| Accounts payable | 3,099 | 1,339 |
| Accrued expenses | (384) | 2,397 |
| Due to related parties | — | (14) |
| Lease liabilities | (276) | 52 |
| **Net cash used in operating activities** | (30,915) | (11,612) |
| **Cash Flows from Investing Activities:** | | |
| Research and development-acquired license | — | (5,000) |
| Capital expenditures | — | (228) |
| **Net cash used in investing activities** | — | (5,228) |
| **Cash Flows from Financing Activities:** | | |
| Proceeds from issuance of common stock from employee stock plans | 242 | — |
| Proceeds from warrants exercised for cash, net of redemption cost | — | 40,671 |
| **Net cash provided by financing activities** | 242 | 40,671 |
| **Effect of exchange rate changes on cash and restricted cash** | 29 | — |
| **Net increase (decrease) in cash and restricted cash** | (30,644) | 23,831 |
| **Cash and restricted cash at beginning of the period** | 111,564 | 61,792 |
| **Cash and restricted cash at end of the period** | **$ 80,920** | **$ 85,623** |
| **Supplemental disclosure of cash flow information:** | | |
| Cash paid for income taxes | $ — | $ — |
| Cash paid for interest | $ — | $ 25 |
| **Supplemental schedule of non-cash investing and financing activities:** | | |
| Reclassification of warrant liabilities to equity due to warrant exercises for cash | $ — | $ 2,503 |
| Right-of-use assets obtained in exchange for operating lease liabilities | $ — | $ 4,166 |

The accompanying notes are an integral part of the unaudited condensed consolidated financial statements.

**VINCERX PHARMA, INC.**
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**
**(UNAUDITED)**

## NOTE 1. NATURE OF BUSINESS

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

The Company is a clinical-stage biopharmaceutical company focused on leveraging its extensive development and oncology expertise to advance new therapies intended to address unmet medical needs for the treatment of cancer. The Company's current pipeline is entirely derived from the Bayer License Agreement (see Note 3), pursuant to which the Company has been granted an exclusive, royalty-bearing, worldwide license under certain Bayer patents and know-how to develop, use, manufacture, commercialize, sublicense and distribute a clinical-stage and follow-on small molecule drug program and a preclinical stage bioconjugation platform, which includes next-generation antibody-drug conjugates and small molecule drug conjugates. The Company intends to use these product candidates to treat various cancers in a patient-specific, targeted approach.

During the early months of 2020, COVID-19 emerged and subsequently spread world-wide. The World Health Organization 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, quarantining people who may have been exposed to the virus and other measures. Our business operations, and those of third parties with whom we conduct business, have been, and could continue to be, adversely affected by the ongoing COVID-19 pandemic. The extent to which COVID-19 could continue to impact our business and operations will depend on future developments that are highly uncertain and cannot be predicted with confidence, such as duration of the pandemic, the emergence and severity of new variants of the virus, additional or modified government actions, new information concerning the severity and impact of the virus, the timing, availability, efficacy, adoption and distribution of vaccines or other preventative treatments, travel restrictions, quarantines, social distancing requirements and business closures and other actions taken to contain the virus or address its impact. Management continues to evaluate the impact of the ongoing COVID-19 pandemic on its current operations and future plans and intends to take appropriate measures to address any such impact, but there can be no assurance that these efforts will be successful and that the pandemic will not continue to have a negative effect on the Company's financial position and results of its operations.

## NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

### Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") for interim financial information and in accordance with the instructions to Form 10-Q and Article 8 of Regulation S-X of the rules and regulations of the SEC. They include the accounts of Vincerx and its wholly-owned subsidiaries VNRX Corp and Vincerx Pharma GmbH. All intercompany accounts and transactions have been eliminated. Certain information or footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted, pursuant to the rules and regulations of the SEC for interim financial reporting. Accordingly, they do not include all the information and footnotes necessary for a complete presentation of financial position, results of operations, or cash flows. In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all adjustments, consisting of a normal recurring nature, which are necessary for a fair presentation of the financial position, operating results and cash flows for the periods presented.

The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the Company's Annual Report on Form 10-K for the year ended December 31, 2021 as filed with the SEC on March 29, 2022, which contains the audited financial statements and notes thereto. The financial information as of December 31, 2021 is derived from the audited financial statements presented in the Company's Annual Report on Form 10-K for the year ended December 31, 2021. The interim results for the three and six months ended June 30, 2022 are not necessarily indicative of the results to be expected for the year ending December 31, 2022 or for any future periods.

### 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 our accrued clinical trial and manufacturing expenses, common stock warrant liabilities and stock-based compensation. The Company bases these estimates on historical experience and on various other assumptions that it believes are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying amounts of assets and liabilities that are not readily apparent from other sources. Actual results could differ materially from those estimates.

**Significant Accounting Policies**

There have been no material changes in the Company's significant accounting policies to those previously disclosed in the Company's Annual Report on Form 10-K.

**Recent Accounting Pronouncements**

In August 2020, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2020-06, Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity, which simplifies accounting for convertible instruments by removing major separation models required under current GAAP. The ASU removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception and it also simplifies the diluted earnings per share calculation in certain areas. The ASU is effective for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2021 and adoption must be as of the beginning of the Company's annual fiscal year. The Company elected to early adopt this guidance on January 1, 2022 without any material impact on its condensed consolidated financial statements.

In May 2021, the FASB issued ASU 2021-04, "Earnings Per Share (Topic 260), Debt-Modifications and Extinguishments (Subtopic 470-50), Compensation-Stock Compensation (Topic 718), and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40)". ASU 2021-04 reduces diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options (for example, warrants) that remain equity classified after modification or exchange. ASU 2021-04 provides guidance for a modification or an exchange of a freestanding equity-classified written call option that is not within the scope of another Topic. It specifically addresses: (1) how an entity should treat a modification of the terms or conditions or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange; (2) how an entity should measure the effect of a modification or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange; and (3) how an entity should recognize the effect of a modification or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange. ASU 2021-04 will be effective for all entities for fiscal years beginning after December 15, 2021. An entity should apply the amendments prospectively to modifications or exchanges occurring on or after the effective date of the amendments. On January 1, 2022, the Company adopted this standard without any material impact on its condensed consolidated financial statements.

**NOTE 3. BAYER LICENSE**

On October 7, 2020, the Company 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, the Company 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 bioconjugation platform, which includes next-generation antibody-drug conjugates and small molecule drug conjugates.

Following the closing of the Business Combination, the Company paid Bayer a $5.0 million upfront license fee on January 5, 2021.

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. As of June 30, 2022, no development and commercial sales milestones under the Bayer License Agreement have been met.

**NOTE 4. RESTRUCTURING**

On June 4, 2022, the Board of Directors of the Company approved a strategic plan to prioritize and focus its resources on its ongoing enitociclib clinical studies for double-hit diffuse large B-cell lymphoma and chronic lymphocytic leukemia and its next generation bioconjugation platform and streamline and realign its resources to support these prioritized studies. This plan includes a reduction of the Company's full-time employees by 33% and other cost reduction measures. Affected employees have been offered separation benefits, including severance payments, payments to cover premiums for continuation of healthcare coverage for a limited period and in some cases vesting acceleration on certain outstanding stock options.

We expect to incur up to approximately $2.5 million of severance and related expenses during 2022, of which approximately $1.2 million has been incurred through June 30, 2022. The estimate of the costs that the Company expects to incur, and the timing of such costs, are subject to a number of assumptions and actual results may differ. The Company may also incur other charges or cash expenditures not currently contemplated due to events that may occur as a result of, or associated with, the strategic plan.

The activity in the accrued restructuring balance, included within accrued expenses on the condensed consolidated balance sheet, was as follows for the three and six months ended June 30, 2022 (in thousands):

| | Restructuring liabilities at December 31, 2021 | Charges | Cash payments | Restructuring liabilities at June 30, 2022 |
|---|---|---|---|---|
| Workforce reduction | $ — | $1,159 | $ (528) | $ 631 |

**NOTE 5. 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 June 30, 2022 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| Liabilities: | | | | |
| Common stock warrant liabilities | $ — | $ — | $ 34 | $ 34 |
| Total fair value | $ — | $ — | $ 34 | $ 34 |

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

The 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 estimated fair value of the private warrants is determined with Level 3 inputs using Black-Scholes and Monte Carlo simulations. There were no changes to the number of private warrants underlying the Level 3 financial instruments during the three- and six-month periods ended June 30, 2022.

There were no transfers between Level 1, 2 or 3 during the three- and six-month periods ended June 30, 2022 and June 30, 2021.

The following table presents changes in Level 3 liabilities measured at fair value for the six-month period ended June 30, 2022. Both observable and unobservable inputs were used to determine the fair value of positions that the Company has classified within the Level 3 category. Unrealized gains and losses associated with liabilities within the Level 3 category include changes in fair value that were attributable to both observable (e.g., changes in market interest rates) and unobservable (e.g., changes in unobservable long-dated volatilities) inputs (in thousands).

| | Warrant Liability |
|---|---|
| **Balance – January 1, 2022** | **$ 6,447** |
| Change in fair value | (6,413) |
| **Balance – June 30, 2022** | **$ 34** |

A summary of the weighted average (in aggregate) significant unobservable inputs (Level 3 inputs) used in measuring the Company's warrant liabilities that are categorized within Level 3 of the fair value hierarchy as of June 30, 2022 and December 31, 2021 is as follows:

| | As of June 30, 2022 | As of December 31, 2021 |
|---|---|---|
| Stock price | $ 1.32 | $ 10.19 |
| Exercise price | $ 11.50 | $ 11.50 |
| Option term (years) | 3.5 | 4.0 |
| Volatility (annual) | 48.6% | 32.5% |
| Risk-free rate | 3.0% | 1.1% |
| Dividend yield (per share) | 0% | 0% |

**NOTE 6. COMMITMENTS AND CONTINGENCIES**

*Leases*

On December 23, 2020, the Company entered into a 5-year term lease agreement which commenced on January 1, 2021. On April 1, 2021, and again on May 1, 2021, the lease was amended to include additional space. The annual rent expense is approximately $1.1 million.

At June 30, 2022, the Company had operating lease liabilities of approximately $3.9 million and right of use assets of approximately $3.5 million, which were included in the condensed consolidated balance sheets.

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

| | For the six months ended June 30, | |
|---|---|---|
| | 2022 | 2021 |
| Lease cost | | |
| Operating lease cost | $598 | $ 83 |
| Variable lease cost | — | — |
| Total operating lease expense | $598 | $ 83 |
| Other information | | |
| Operating cash flows from operating leases | $438 | $ 70 |
| Right-of-use assets obtained in exchange for operating lease liabilities | $— | $ 4,166 |
| Weighted-average remaining lease term – operating leases | 3.5 | 4.5 |
| Weighted-average discount rate – operating leases | 8% | 8% |

As of June 30, 2022, future minimum payments during the next three years are as follows (in thousands):

| | |
|---|---|
| Remaining period ended December 31, 2022 | $ 608 |
| Year ended December 31, 2023 | 1,261 |
| Year ended December 31, 2024 | 1,284 |
| Year ended December 31, 2025 | 1,336 |
| Total | 4,489 |
| Less present value discount | (591) |
| Operating lease liabilities included in the Condensed Consolidated Balance Sheet at June 30, 2022 | $3,898 |

## NOTE 7. 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 June 30, 2022 and December 31, 2021, there were 21,189,769 shares and 21,057,560 shares, respectively, of common stock outstanding, and no shares of preferred stock outstanding.

### Restricted Shares

A summary of restricted stock activity for the three- and six-months ended June 30, 2022 and June 30, 2021 is presented below:

| | Number of Shares | Weighted Average Grant Date Fair Value per Share |
|---|---|---|
| **Nonvested at January 1, 2022** | **182,686** | **$ 0.045** |
| Vested | (33,203) | — |
| **Nonvested at March 31, 2022** | **149,483** | **0.049** |
| Vested | (27,493) | **—** |
| **Nonvested at June 30, 2022** | **121,990** | **$ 0.052** |

| | Number of Shares | Weighted Average Grant Date Fair Value per Share |
|---|---|---|
| **Nonvested at January 1, 2021** | **361,168** | **$ 0.036** |
| Vested | (44,621) | — |
| **Nonvested at March 31, 2021** | **316,547** | **0.037** |
| Vested | (44,620) | — |
| **Nonvested at June 30, 2021** | **271,927** | **$ 0.041** |

As of June 30, 2022, there was approximately $6,600 of unrecognized stock-based compensation related to restricted stock that will be amortized in 2.0 years.

### Warrants

As of June 30, 2022, there were 3,295,000 private warrants to purchase common stock outstanding. No public warrants remain outstanding at June 30, 2022.

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

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

The previously outstanding public warrants and the private warrants issued to LifeSci Holdings LLC that were amended as described above were determined to be equity classified in accordance with ASC 815, Derivatives and Hedging. The remaining private warrants were determined to be liability classified in accordance with ASC 815, Derivatives and Hedging (see note 5).

## NOTE 8. EQUITY INCENTIVE PLANS

In connection with the Business Combination, the stockholders approved the Vincerx Pharma, Inc. 2020 Stock Incentive Plan (the "2020 Plan"), which became effective upon the closing of the Business Combination on December 23, 2020. As of June 30, 2022, the Company had 4,542,924 shares of common stock reserved for issuance and 599,546 options to acquire common stock that are available to grant, 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 2020 Plan is as follows (amounts in thousands, except per share amounts):

| | Stock Options | Weighted Average Exercise Price | Weighted Average Remaining Contractual Life (in years) | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Outstanding at January 1, 2022 | 3,408 | $ 18.74 | 9.2 | $ 3 |
| Options granted | 1,166 | 5.62 | 10.0 | — |
| Options cancelled | (631) | 15.58 | — | — |
| Outstanding at June 30, 2022 | 3,943 | $ 15.37 | 8.5 | $ — |
| Options vested and exercisable at June 30, 2022 | 1,916 | $ 18.84 | 7.8 | $ — |

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.

As of June 30, 2022, the Company had stock-based compensation of approximately $9.5 million related to unvested stock options not yet recognized that are expected to be recognized over an estimated weighted average period of 1.0 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 six months ended June 30, 2022 and 2021:

| | For the six months ended June 30, | |
|---|---|---|
| | 2022 | 2021 |
| Exercise price | $5.62 | $19.02 |
| Expected term (years) | 6.0 | 5.9 |
| Volatility (annual) | 83.6% | 75.5% |
| Risk-free rate | 3.0% | 0.9% |
| Dividend yield (per share) | 0% | 0% |

Total stock-based compensation expense recognized in the three- and six-months ended June 30, 2022 and 2021 was as follows (amounts in thousands):

| | For the three months ended | | For the six months ended | |
|---|---|---|---|---|
| | June 30, 2022 | June 30, 2021 | June 30, 2022 | June 30, 2021 |
| Research and development | $ 2,200 | $ 4,401 | $ 5,684 | $ 7,078 |
| General and administrative | 1,162 | 2,236 | 2,936 | 4,274 |
| **Total stock-based compensation expense** | **$ 3,362** | **$ 6,637** | **$ 8,620** | **$ 11,352** |

## NOTE 9. 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 three- and six-months ended June 30, 2022 and 2021 (amounts in thousands, except per share number):

| | For the three months ended June 30, | | For the six months ended June 30, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| **Numerator:** | | | | |
| Net loss | $ (18,421) | $ (2,034) | $(34,845) | $ (8,310) |
| **Denominator:** | | | | |
| Weighted average common shares outstanding, basic and diluted | 20,995 | 16,350 | 20,946 | 15,050 |
| Net loss per common share, basic and diluted | $ (0.88) | $ (0.12) | $ (1.66) | $ (0.55) |

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 (amount in thousands):

| | For the three and six months ended June 30, | |
|---|---|---|
| | 2022 | 2021 |
| Options outstanding | 3,943 | 3,172 |
| Warrants | 3,295 | 3,295 |
| Total | 7,238 | 6,467 |

**NOTE 10. SUBSEQUENT EVENT**

In connection with our strategic plan and workforce reduction (see note 4), the Company has consolidated its leased office space at its corporate headquarters location. Effective July 8, 2022, the Company has subleased substantially all of its remaining unused office space for a term of 18 months at a base rent of $50,000 per month.

## ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The below discussion should be read in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations and the audited consolidated financial statements and notes thereto for the year ended December 31, 2021 included in our Annual Report on Form 10-K for the year ended December 31, 2021 and with the financial statements and the notes thereto contained elsewhere in this report. Certain information contained in the discussion and analysis set forth below includes forward-looking statements that involve risks and uncertainties.

### Overview

We are a clinical-stage biopharmaceutical company focused on leveraging our extensive development and oncology expertise to advance new therapies intended to address unmet medical needs for the treatment of cancer. Our current pipeline is entirely derived from the Bayer License Agreement, pursuant to which we have been granted an exclusive, royalty-bearing, worldwide license under certain Bayer patents and know-how to develop, use, manufacture, commercialize, sublicense and distribute (i) a clinical-stage and follow-on small molecule drug program and (ii) a preclinical stage bioconjugation platform, which includes next-generation antibody-drug conjugates and small molecule drug conjugates. 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. Our small molecule drug program includes enitociclib, which is a highly selective, clinical-stage PTEFb/CDK9 inhibitor. Our ADC platform includes VIP943 and VIP924, 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.

### 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 the discussion below under "Liquidity and Capital Resources."

### Basis of Presentation

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

**Components of Results of Operations**

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

***Revenue***

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

***Research and Development Expense***

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

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

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We anticipate that our research and development expenses will increase in the future as we continue to develop our product candidates and manufacturing processes and conduct discovery and research activities for our preclinical and clinical programs. We cannot determine with certainty the timing of initiation, the duration or the completion costs of current or future preclinical studies and clinical trials of our product candidates due to the inherently unpredictable nature of preclinical and clinical development. Clinical and preclinical development timelines, the probability of success and development costs can differ materially from expectations. We anticipate that we will make determinations as to which product candidates to pursue and how much funding to direct to each product candidate on an ongoing basis in response to the results of ongoing and future preclinical studies and clinical trials, regulatory developments 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, including the impact of factors such as inflation, supply chain disruptions and the ongoing COVID-19 pandemic;
- per patient clinical trial costs, including based on the number of doses that patients receive and the cost of drug products for combination therapies;
- the number of patients who enroll in each clinical trial;
- the number of clinical trials required for approval;
- the number of sites included in the clinical trials;
- the countries in which the clinical trials are conducted;
- the length of time required to enroll eligible patients;

- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the clinical trials and follow-up;
- the phase of development of the product candidate;
- third party contractors failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- the cost of insurance, including product liability insurance, in connection with clinical trials;
- regulators or institutional review boards requiring that we or our investigators suspend or terminate clinical development for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks; and
- the efficacy and safety profile of our product candidates.

***General and Administrative Expenses***

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

We anticipate that our general and administrative expenses will increase in the future as we expand our operations and infrastructure to support the initiation, continuation and expansion of our preclinical studies and clinical trials for our product candidates. We also anticipate that our general and administrative expenses will increase as a result of payments for accounting, audit, legal and consulting services, as well as costs associated with maintaining compliance with Nasdaq listing rules and SEC requirements, director and officer liability insurance, investor and public relations activities and other expenses associated with operating as a public company.

***Change in Fair Value of Warrant Liabilities***

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

**Results of Operations**

***Comparison of the Three and Six Months Ended June 30, 2022 and 2021***

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

| | For the three months ended June 30, | | |
|---|---|---|---|
| | 2022 | 2021 | Amount Change |
| **Operating expenses:** | | | |
| General and administrative | $ 4,722 | $ 6,695 | $ (1,973) |
| Research and development | 13,742 | 10,698 | 3,044 |
| Restructuring | 1,159 | — | 1,159 |
| Total operating expenses | 19,623 | 17,393 | 2,230 |
| **Loss from operations** | (19,623) | (17,393) | (2,230) |
| Other income | | | |
| Change in fair value of warrant liabilities | 1,202 | 15,359 | (14,157) |
| Total other income | 1,202 | 15,359 | (14,157) |
| **Net loss** | **$ (18,421)** | **$ (2,034)** | **$ (16,387)** |

| | For the six months ended June 30 | | |
|---|---|---|---|
| | 2022 | 2021 | Amount Change |
| **Operating expenses:** | | | |
| General and administrative | $ 10,378 | $ 11,486 | $ (1,108) |
| Research and development | 29,713 | 15,532 | 14,181 |
| Restructuring | 1,159 | — | 1,159 |
| Total operating expenses | 41,250 | 27,018 | 14,232 |
| **Loss from operations** | (41,250) | (27,018) | (14,232) |
| Other income (expense) | | | |
| Change in fair value of warrant liabilities | 6,413 | 18,708 | (12,295) |
| Other expense | (8) | — | (8) |
| Total other income (expense) | 6,405 | 18,708 | (12,303) |
| **Net loss** | **$ (34,845)** | **$ (8,310)** | **$ (26,535)** |

***Research and Development***

Research and development expenses increased by approximately $3.0 million and $14.2 million, respectively, for the three and six months ended June 30, 2022 compared to the three and six months ended June 30, 2021. The increase for the six months ended June 30, 2022 compared to the same period in 2021 primarily related to increases in manufacturing services of approximately $5.5 million, including the initiation of manufacturing associated with our ADC program, new employee salaries of approximately $2.4 million, third party research and preclinical work of approximately $4.6 million, and clinical services of approximately $3.1 million, partially offset by a decline in stock-based compensation of approximately $1.4 million.

***General and Administrative***

General and administrative expenses decreased by approximately $2.0 million and $1.1 million, respectively, for the three and six months ended June 30, 2022 compared to the three and six months ended June 30, 2021, primarily as a result of declines in stock-based compensation expense of $1.1 million and $1.3 million for the three- and six-month periods, respectively.

***Restructuring***

On June 4, 2022, the Board of Directors of the Company approved a strategic plan to prioritize and focus its resources on its ongoing enitociclib clinical studies for double-hit diffuse large B-cell lymphoma and chronic lymphocytic leukemia and its next generation bioconjugation platform and streamline and realign its resources to support these prioritized studies. This plan includes a reduction of the Company's full-time employees by 33% and other cost reduction measures. Affected employees have been offered separation benefits, including severance and reimbursement of healthcare premium payments.

We have incurred approximately $1.2 million of severance and related expenses through June 30, 2022.

***Change in Fair Value of Warrant Liabilities***

The change in fair value of warrant liabilities was primarily due to the decrease in the closing price of our common stock from $10.19 as of December 31, 2021 to $1.32 as of June 30, 2022.

**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 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. 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. At June 30, 2022, we had approximately $80.9 million in cash. We intend to devote our capital resources 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. In June 2022, our board of directors approved a strategic plan to prioritize and focus our resources on our ongoing enitociclib clinical studies for double-hit DLBCL and CLL and our next generation bioconjugation platform and to streamline and realign our resources, including a 33% workforce reduction, to support these prioritized studies and programs and extend our estimated cash runway. Based on our current business plans and assumptions, we believe our existing cash will enable us to fund our operating expenses and capital requirements into late 2024. Our estimate as to how long we expect our capital to be able to fund our operating expenses and capital requirements is based on plans and assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could result in less cash available to us or cause us to consume capital significantly faster than we currently anticipate, and we may need or choose to seek additional funds sooner than planned.

Because of the numerous risks and uncertainties associated with research, development, manufacturing, clinical trials 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 research activities, clinical trials, 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. 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, or at all, particularly in light of current economic or market conditions. We do not have any committed external source of funds. Market volatility resulting from the COVID-19 pandemic, current economic and market conditions and the Russian invasion of Ukraine, or other factors, could also adversely impact our ability to access capital as and when needed. Our failure to raise capital as and when needed or on acceptable terms would have a negative impact on our financial condition and our ability to pursue our business strategy, and we may have to delay, reduce the scope of, suspend or eliminate one or more of our research-stage programs, clinical trials or future commercialization efforts.

The COVID-19 pandemic continues to evolve, and as a result, we are continuing to assess the effect that it could 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 duration of the pandemic, the emergence and severity of new variants of the virus, additional or modified government actions, new information concerning the severity and impact of the virus, the timing, availability, efficacy, adoption and distribution of vaccines or other preventative treatments, travel restrictions, quarantines, social distancing requirements and business closures, and other actions taken to contain the virus or address its impact. We do not yet know the full extent of potential delays or impacts on our business and operations, our clinical trials, our research programs, healthcare systems or the global economy. While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, it could result in a recession or other significant disruption of global financial markets, reducing our ability to access capital, which could negatively affect our liquidity, 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 six months ended June 30, | |
|---|---|---|
| | 2021 | 2021 |
| Net cash used in operating activities | $(30,915) | $(11,612) |
| Net cash used in investing activities | $ — | $ (5,228) |
| Net cash provided by financing activities | $ 242 | $ 40,671 |

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

Net cash used in operating activities was approximately $30.9 million for the six months ended June 30, 2022, consisting primarily of payments to clinical and manufacturing service providers, internal payroll costs and third-party professional services as we build our public company infrastructure and prepare for and conduct our clinical trials. Our net loss during the six months ended June 30, 2022 was approximately $34.8 million, which included approximately $8.6 million related to stock-based compensation and offset by approximately $6.4 million related to the change in fair value of warrant liabilities.

### 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 discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect our reported amounts of assets, liabilities, revenues and expenses.

On an ongoing basis, we evaluate our estimates and judgments, including those related to derivative liabilities, accrued expenses and stock-based compensation. We based our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the reported amounts of revenues and expenses that are not readily apparent from other sources. Actual results could differ from those estimates, particularly given the significant social and economic disruptions and uncertainties associated with the ongoing COVID-19 pandemic and the other risks and uncertainties set forth in this report in the section entitled “Risk Factors.”

Our critical accounting policies and significant estimates are detailed in our Annual Report on Form 10-K for the year ended December 31, 2021. Our critical accounting policies and significant estimates have not changed substantially from those previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2021.

## ITEM 3. Quantitative and Qualitative Disclosures About Market Risk.

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

### Interest Rate Risk

Cash and restricted cash 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 condensed 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 condensed consolidated financial statements.

## ITEM 4. Controls and Procedures

### Evaluation of Disclosure Controls and Procedures

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

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

**Changes in Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) for the three months ended June 30, 2022 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## PART II

### ITEM 1. 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 1A. Risk Factors.

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

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

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

The Bayer License Agreement imposes on us obligations relating to development, commercialization, funding, payment, diligence, intellectual property protection and other matters. We paid Bayer an upfront license fee of $5.0 million following the closing of the Business Combination. In addition, we are obligated to make significant future payments to Bayer upon the achievement of certain development and commercial sales milestones involving licensed products. The size and timing of these milestone payments will vary greatly depending on factors such as the particular licensed product, whether it involves a 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.

***Our preclinical development, clinical trials, manufacturing, supply chains and other operations and business activities, and the operations and business activities of third parties with whom we conduct business, including our contract manufacturers, contract research organizations, shippers, clinical trial sites and others, have been, and continue to be, adversely affected by the effects of epidemics, including the ongoing COVID-19 pandemic.***

Our business has been, and could continue to be, adversely affected by health epidemics, including the ongoing COVID-19 pandemic, 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, shippers, clinical trial sites 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 has affected, and may continue to affect, employees, patients, communities and business operations, as well as the U.S. economy and financial markets. Many geographic regions, including those in which we and the third parties on whom we rely conduct operations, imposed, and in the future may again impose, “shelter-in-place,” quarantines or similar orders or restrictions to control the spread of COVID-19. These measures negatively impacted our productivity, disrupted our business, delayed our preclinical and clinical programs and timelines, and limited our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations, now or in the future, could negatively impact our business, operating results and financial condition.

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

If our relationships with our suppliers or other vendors are delayed, scaled back or terminated as a result of 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 have been, and may continue to be, delayed due to staffing shortages, prioritization of hospital resources toward the COVID-19 pandemic or concerns among patients about participating in clinical trials during a pandemic or public health measures imposed by governmental authorities in the countries and regions in which the clinical sites are located. Some patients may have difficulty following certain aspects of clinical trial protocols if quarantines or other restrictive measures impede patient movement or interrupt healthcare services. Similarly, our inability to successfully recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure 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 have impacted, and could continue to impact, our operations.

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

Our future success is dependent in large part on our ability to timely complete clinical trials, obtain marketing approval for and successfully commercialize enitociclib, our lead product candidate. We believe our highly selective CDK9 inhibitor, enitociclib, is differentiated from other CDK9 inhibitor technologies being developed by our competitors and are investing significant efforts and financial resources in the research and development of enitociclib. We are conducting a Phase 1 trial of enitociclib as a monotherapy in patients with double-hit DLBCL and CLL and in combination with BTKi in patients with CLL. enitociclib 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 enitociclib, 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 enitociclib will depend on several factors, including the following:

- the efficacy of enitociclib at selectively targeting CDK9;
- the successful and timely completion of our ongoing clinical trials of enitociclib;
- the initiation and successful patient enrollment and completion of additional clinical trials of enitociclib on a timely basis;
- establishing and maintaining relationships with contract research organizations and clinical sites for the clinical development of enitociclib in the United States and internationally;
- the frequency and severity of adverse events in the clinical trials;
- achieving dose selection, efficacy, safety and tolerability profiles that are satisfactory to the FDA or any comparable foreign regulatory authority for marketing approval;
- establishing and maintaining supply arrangements with third-party drug product suppliers, manufacturers and distributors;

- obtaining and maintaining patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- a continued acceptable safety profile following any marketing approval; and
- our ability to compete with other therapies.

We do not have 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 enitociclib, which would materially harm our business.

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

enitociclib 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 enitociclib may present novel issues that could cause delays in development or approval. While results from preclinical data and early clinical trials of enitociclib have shown tolerable side effects and a reduction in MCL1 and MYC mRNA, enitociclib may not demonstrate in patients any or all of the pharmacological benefits we believe it may possess. We have not yet succeeded and may never succeed in demonstrating efficacy and safety for enitociclib in pivotal clinical trials or in obtaining marketing approval thereafter. For example, although Bayer has evaluated enitociclib in preclinical studies and in early-stage clinical trials, enitociclib 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 enitociclib. If we cannot replicate the positive results from Bayer's Phase 1 clinical trials in our clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize enitociclib. As a result, our focus on exploring PTEFb/CDK9 inhibition may fail to result in the identification of viable additional indications for enitociclib. If we are unsuccessful in our development efforts, we may not be able to advance the development of or commercialize enitociclib, 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 any sooner than late 2022 or early 2023, 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 (an optimized CPT payload derived from SN38, a well-known cytotoxic drug and active metabolite of irinotecan) or an ADC using KSPi and CellTrapper. We may uncover a previously unknown risk associated with KSPi or our optimized CPT payload, our CellTrapper technology may not be as impermeable as initial testing suggests, our linker technology may not be as effective as initial testing suggests, or other issues that may be more problematic than we currently believe, which may prolong the period of observation required for obtaining, or result in the failure to obtain, regulatory approval or may necessitate additional preclinical and clinical testing. While results from preclinical trials of VIP943, VIP924 and VIP236 in mouse xenograft models have shown proof-of-concept for each, VIP943, VIP924 and VIP236 may not demonstrate in patients any or all of the pharmacological benefits we believe they may possess. If the KSPi warhead or optimized CPT payload that we use is not safe in certain product candidates, we would be required to abandon or redesign all of our current lead ADC or SMDC product candidates. We have not yet succeeded and may never succeed in demonstrating efficacy and safety of VIP943, VIP924 and VIP236 in pivotal clinical trials or in obtaining marketing approval thereafter. 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 an optimized CPT 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) enitociclib in the ongoing Phase 1 clinical trials or in larger-scale clinical trials or (ii) VIP943, VIP924 or VIP236 in preclinical studies, clinical trials or in large-scale clinical trials. Advancing enitociclib as a PTEFb/CDK9 inhibitor, VIP943 and VIP924 as ADCs delivering a KSPi warhead, or VIP236 as an SMDC delivering an optimized CPT payload creates significant challenges for us, including:

- obtaining marketing approval, as the FDA or other regulatory authorities have never approved a CDK9 inhibitor, KSPi warhead or SMDC delivering an optimized CPT 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.

***We rely in part 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 in part 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 enitociclib, 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 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, increase the cost of or prevent regulatory approval for our product candidates.

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

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

The success of other product candidates we may develop will depend on many factors, including the following:

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

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

Positive and promising results from preclinical studies and early-stage clinical trials may not be predictive of results from late-stage clinical trials or from clinical trials of the same product candidates for the treatment of other indications. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Late-stage clinical trials could differ in significant ways from early-stage clinical trials, including changes to inclusion and exclusion criteria, efficacy endpoints, dosing regimen and statistical design. Moreover, success in clinical trials in a particular indication does not guarantee that a product candidate will be successful for the treatment of other indications. Many companies in the biotechnology industry have suffered significant setbacks in late-stage clinical trials after achieving encouraging or positive results in early-stage development. There can be no assurance that we will not face similar setbacks in our ongoing clinical trials or planned late-stage clinical trials, including 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.***

Our competitors are developing a large number of drug candidates 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 these drug candidates, existing therapies and new therapies that may become available in the future. We believe that a significant number of products are currently under development, and may become commercially available in the future, for the treatment of conditions for which we may attempt to develop product candidates. Several pharmaceutical and biotechnology companies have CDK9 inhibitors, ADCs, SMDCs, immunotherapies 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 and may have begun developing their drug candidates earlier than us. Our competitors may also have more experience:

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

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

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

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

***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 efficacy of our products, our manufacturing processes and facilities or our marketing programs. FDA or other regulatory authority investigations could potentially lead to a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our products, injury to our reputation, costs to defend the related litigation, a diversion of management's time and our resources and substantial monetary awards to clinical trial participants or patients. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive and difficult to obtain. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have an adverse effect on our business and financial condition. In addition, any inability or delay in obtaining such insurance could negatively impact our ability to conduct clinical trials on a timely basis or at all. 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 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 enitociclib, 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 enrollment and other delays and may be required to continue beyond our available funding, and we cannot be certain that we will be able to raise sufficient funds to successfully complete the development, clinical trials and commercialization of any of our product candidates currently in preclinical and clinical development, should they succeed.***

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

- delays in securing clinical investigators and trial sites for our clinical trials;
- delays in obtaining Institutional Review Board, and regulatory approvals to commence a clinical trial;
- slower than anticipated rates of patient recruitment and enrollment, or not reaching the targeted number of patients, because of competition for patients from other trials, difficulty identifying patients with our proposed indications, the impact of the COVID-19 pandemic or other health epidemics or limited or no availability of coverage, reimbursement or 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 could arise as a result of incompletely explored pharmacokinetic and pharmacodynamics behaviors or initiatives such as the FDA's Project Optimus;
- approval and introduction of new therapies or changes in standards of practice or regulatory guidance that render our clinical trial endpoints or the targeting of our proposed indications less attractive;
- inability to monitor patients adequately during or after treatment or problems with investigator or patient compliance with the trial protocols;
- inability to replicate in large controlled studies safety and efficacy data obtained from a limited number of patients in uncontrolled trials;
- inability or unwillingness of medical investigators to follow our clinical protocols; and
- unavailability of clinical trial supplies.

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

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

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

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

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.

***We recently implemented certain workforce and cost reduction measures in connection with our strategic plan, and there can be no assurance that we will be able to successfully implement these workforce and cost reductions or that such measures will not adversely affect our business.***

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

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

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

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

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

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

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

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

In addition, we must comply with increasingly complex, rigorous and sometimes conflicting laws, regulations and standards enacted to protect business and personal data in the United States, Europe and elsewhere. For example, the European Union adopted the General Data Protection Regulation (the "GDPR"), which became effective in 2018, the United Kingdom adopted the Data Protection Act 2018 (as updated), which became effective in 2018, and California adopted the California Consumer Privacy Act (the "CCPA"), which became effective in 2020. These laws impose additional obligations on companies regarding the handling of personal data and provide certain individual privacy rights to persons whose data is stored. Compliance with existing, proposed and recently enacted laws, regulations and standards (including implementation of the privacy and process enhancements called for under GDPR and CCPA) can be costly and time consuming, and any failure to comply with these laws, regulations and standards could subject us to legal and reputational risks. Misuse of or failure to secure personal information, including any breach, loss or compromise of clinical trial participant personal data, could also result in violation of data privacy laws, regulations and standards, proceedings against the Company by governmental entities or others, imposition of fines by governmental authorities and damage to our reputation and credibility and could have a negative impact on our business and operations.

**Risks Related to Our Financial Position and Need for Additional Capital**

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

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

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

We have incurred net losses in each reporting period since our inception, have not generated any revenue from product sales to date and have financed our operations principally through the sale of our equity securities. Our losses have resulted principally from expenses incurred in connection with licensing our product candidates from Bayer, raising capital, building our management team and business infrastructure and conducting preclinical studies and early clinical trials. Our lead product candidate, enitociclib, is in Phase 1 clinical trials, and we intend to continue its clinical development in patients with double-hit DLBCL and CLL to obtain clinical proof-of-concept in indications with unmet medical needs by mid-2023. Our lead ADC product candidates, VIP943 and VIP924, are in preclinical development, and we do not expect the first to begin clinical trials until late 2023 or early 2024. Our SMDC product candidate, VIP236, is in preclinical development, and we do not expect it to begin clinical trials until late 2022 or early 2023. 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, enitociclib, 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 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 enitociclib, 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.

As of June 30, 2022, we had approximately $80.9 million in cash. We intend to use our existing cash to advance and expand our preclinical and clinical programs, including to fund additional monotherapy and combination clinical studies for our product candidates, to fund certain of the milestone payments under the Bayer License Agreement and our public company compliance costs and for working capital and other general corporate purposes. In June 2022, our board of directors approved a strategic plan to prioritize and focus our resources on our ongoing enitociclib clinical studies for double-hit DLBCL and CLL and our next generation bioconjugation platform and to streamline and realign our resources, including a 33% workforce reduction, to support these prioritized studies and programs and extend our estimated cash runway. Based on our current business plans and assumptions, we believe that our existing cash will be sufficient to fund our operating expenses and capital expenditure requirements into late 2024. Our estimate as to how long we expect our existing cash to be able to continue to fund our operating expenses and capital expenditure requirements is based on plans and assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could result in less cash available to us or cause us to consume capital significantly faster than we currently anticipate, and we may need or choose to seek additional funds sooner than planned.

We will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources, which may dilute our stockholders or restrict our operating activities. Raising additional funds by issuing equity or convertible debt securities may cause our stockholders to experience substantial dilution. Raising additional funds through debt financing may involve covenants that restrict our business activities and options. To the extent that we raise additional funds through collaborations and licensing arrangements, we may have to relinquish valuable rights to our drug discovery and other technologies, development programs or product candidates, or grant licenses on terms that may not be favorable to us. Additional funding may not be available to us on favorable terms, or at all, particularly in light of the current economic and market conditions. We do not have any committed external source of funds. Market volatility resulting from the continuing COVID-19 pandemic, the war in Ukraine or other factors could also adversely impact our ability to access capital as and when needed. Our failure to raise capital as and when needed or on acceptable terms would have a negative impact on our financial condition and our ability to pursue our business strategy, and we may have to delay, reduce the scope of, suspend or eliminate one or more of our 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 enitociclib, 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 our 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 application, a BLA or an NDA to the FDA, manufacturing clinical trial supplies and completing clinical trials for our product candidates, our expenses could increase substantially and our ability to achieve profitability could be further delayed. As we obtain certain developmental, regulatory and sales milestones, we will be responsible for contingent 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, dose selection, efficacy, approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, marketing and distribution. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process must be successfully completed in the United States and in many foreign jurisdictions before a new drug can be marketed. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. We cannot provide any assurance that any product candidate we may develop will progress through required clinical testing and obtain the regulatory approvals necessary for us to begin selling them.

We have not conducted, managed or completed large-scale or pivotal clinical trials nor managed the regulatory approval process with the FDA or any other regulatory authority with respect to our product candidates. The time required to obtain approvals from the FDA and other regulatory authorities is unpredictable and requires successful completion of extensive clinical trials which typically takes many years, depending upon the type, complexity and novelty of the product candidate. The standards that the FDA and its foreign counterparts use when evaluating clinical trial data can and often does change during drug development, which makes it difficult to predict with any certainty how they will be applied. We may also encounter unexpected delays or increased costs due to new government regulations, including future legislation or administrative action, changes in policy or new initiatives during the period of drug development, clinical trials and FDA regulatory review. For example, in the U.S., the FDA's Project Optimus initiative will transform the dose-finding and dose optimization paradigm across oncology to emphasize selection of a dose or doses that maximizes not only the efficacy of a drug but the safety and tolerability as well, which could increase the development time and costs of our clinical trials. In addition, the European Union began transitioning to full implementation of the EU Clinical Trials Regulation in January 2022, and the United Kingdom's Medicines and Healthcare products Regulatory Agency has begun to transition the U.K. to a fully independent clinical trial regulatory framework following Brexit, both of which could result in significant uncertainties and delays.

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

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

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

If our product candidates are associated with a high and unacceptable severity and prevalence of side effects or unexpected characteristics in preclinical studies or clinical trials when used alone or in combination with other approved products or investigational new drugs, we may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Such results could result in a more restrictive label, implementation of a Risk Evaluation and Mitigation Strategy or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities and may prevent us from achieving or maintaining market acceptance of the affected product candidate 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 clinical trials, or we may be required to abandon the clinical 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 trials may also develop after such approval and lead to a requirement to conduct additional clinical safety trials, additional contraindications, warnings and precautions being added to the drug label, implementation of a Risk Evaluation and Mitigation Strategy, significant restrictions on the use of the product or the withdrawal of the product from the market. We cannot predict whether our product candidates will cause toxicities in humans that would preclude or lead to the revocation of regulatory approval based on preclinical studies or early-stage clinical trials.

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

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing 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 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 or BLA for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent FDA feedback we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval or receive an expedited regulatory designation (e.g., breakthrough therapy designation) for our product candidates, there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA or other comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product 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.

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

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

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

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

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal healthcare laws, commonly referred to as "fraud and abuse" laws, have been applied in recent years to restrict certain marketing practices in the pharmaceutical industry. Other jurisdictions, such as Europe, have similar laws. These laws include false claims and anti-kickback statutes. Anti-kickback laws make it illegal for a manufacturer to offer or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase of a product. The 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 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. 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 to a significant extent upon previous development conducted by Bayer or other third parties over whom we had no control and before we in-licensed the product candidates. To receive regulatory approval of a product candidate, we must present all relevant data and information obtained during its development, including research conducted prior to our licensure of the product candidate. Although we are not currently aware of any such problems, any problems that emerge with preclinical or clinical development conducted prior to our in-licensing may affect future results or our ability to document prior development and to conduct clinical trials, which could delay, limit or prevent regulatory approval for our product candidates.

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

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

If the FDA or comparable foreign regulatory authorities approve any of our product candidates for commercial sale, or if we significantly expand our clinical trials, we will need to manufacture them in larger quantities, and we may not be able to successfully increase the manufacturing capacity for any of our product candidates in a timely or economic manner, or at all. Until such time, if any, that we directly control the manufacturing of our product candidates, we will have limited control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel, and we will be dependent on our third-

party manufacturing partners for compliance with current cGMP requirements for the manufacture of our product candidates. If our third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable foreign regulatory authorities, we will not be able to secure or maintain regulatory approval for our product candidates. In addition, if any third-party manufacturer makes improvements in the manufacturing process for our product candidates, we may not own, or may have to share, the intellectual property rights to such innovations.

Any inability to identify and retain third-party manufacturers or any performance failure on the part of such manufacturers, or a disruption in our supply chain as a result of political unrest, trade disputes, natural disasters, pandemics, climate change or otherwise, could delay our clinical trials and development, regulatory approval of our product candidates, commercialization of our product candidates or our ability to sell our commercial products, resulting in additional losses and depriving us of potential product revenues.

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

An important element of our strategy for developing, manufacturing and commercializing our product candidates is entering into collaborative arrangements or strategic alliances with pharmaceutical companies, research institutions or other industry participants to advance our programs and enable us to maintain our financial and operational capacity. We face significant competition in seeking appropriate 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 agreement, including the Bayer License Agreement, we may be required to pay damages and could lose intellectual property rights that are necessary for developing and protecting our product candidates.***

Pursuant to the Bayer License Agreement, we have been granted a license from Bayer to certain intellectual property rights covering enitociclib, 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 enitociclib, 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 enitociclib under the Bayer License Agreement, we do not have issued patents covering our other product candidates and we may need additional issued patents covering enitociclib. We cannot be certain that the claims in our other U.S. pending patent applications, corresponding international patent applications and patent applications in certain foreign territories, or those of our licensors, will be considered patentable by the USPTO, courts in the 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 and obtain patent protection.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, one or more of our patents or in-licensed patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984. The Drug Price Competition and Patent Term Restoration Act of 1984 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 the federal and state laws of the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as 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.

Geopolitical actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution, maintenance or enforcement of our patent applications or issued patents or those of any current or future licensors. For example, United States and foreign government actions related to Russia's invasion of Ukraine may limit or prevent filing, prosecution and maintenance of patent applications and issued patents in Russia, and actions by the Russian government would allow Russian companies and individuals to exploit inventions owned by patentees from the United States without consent or compensation. These actions could adversely affect our business.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, 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 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 enitociclib in certain treatment indications. While we believe that these patents are difficult to enforce and that we would have valid defenses to these claims of patent infringement, we cannot be certain that we would prevail in any dispute and we cannot be certain how an adverse determination would affect our business.

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

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

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

- 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 our 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 our current and future product candidates;
- commencement of, or involvement in, litigation involving us;
- our capital requirements and capital raising activities, such as issuances of securities or the incurrence of 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 shares of common stock by our directors, executive officers or significant stockholders, or the perception that such sales could occur; and
- general economic and political conditions such as recessions, interest rates, fuel prices, international currency fluctuations and acts of war or terrorism.

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

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

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

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

Pursuant to the Voting and Support Agreement entered into among the Legacy Holders and certain other stockholders in connection with the Business Combination (the "Voting Agreement"), the Legacy Holders, including Dr. Ahmed M. Hamdy, our Chief Executive Officer, and Dr. Raquel E. Izumi, our President and Chief Operations Officer, have the right to designate seven of the nine members to our board of directors, and the stockholders who are parties to the Voting Agreement, who beneficially owned, as of July 31, 2022, approximately 31% of our outstanding common stock, have agreed to vote for such designees. As a result, the Legacy Holders have the ability to exercise significant influence over the election of our board of directors, which in turn may create issues if and to the extent our interests and those of these stockholders diverge. We have not established at this time any procedural mechanisms to address actual or perceived conflicts of interest of such directors and officers and expect that our board of directors, in the exercise of its fiduciary duties, will determine how to address any actual or perceived conflicts of interest on a case-by-case basis.

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

If we fail to meet the continued listing requirements and Nasdaq delists 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 the market price of our common stock.***

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities.

As of June 30, 2022, private warrants to purchase 3,295,000 shares of common stock were outstanding. Additionally, up to 6,000,000 Earnout Shares may be issued in connection with the Merger Agreement, provided that certain conditions are met. To the extent such private warrants are exercised or conditions to receive Earnout Shares are met, additional shares of our common stock will be issued, which will result in dilution to the holders of our common stock and increase the number of shares eligible for resale in the public market. Such shares are eligible for sale in the public market, subject to volume limitations under Rule 144 under the Securities Act with respect to shares held by directors, executive officers and other affiliates, and certain of such shares are eligible for sale in the public market under our currently effective Registration Statement on Form S-3. In addition, in September 2021, we sold 3,500,000 shares of our common stock to certain investors in a private placement, and such shares are available for resale under our Registration Statement on Form S-3. Sales, or potential sales, of substantial numbers of shares in the public market could increase the volatility of the market price of our common stock or adversely affect the market price of our common stock.

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

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

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

We are an emerging growth company, as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including exemption from compliance with the auditor attestation requirements of Section 404, reduced disclosure obligations regarding executive compensation 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 federal 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 stockholders from influencing significant corporate decisions.***

As of July 31, 2022, 2022, Dr. Ahmed M. Hamdy, our Chief Executive Officer, and Dr. Raquel E. Izumi, our President and Chief Operations Officer, beneficially owned, directly or indirectly, approximately 16% of our outstanding common stock, and our directors and executive officers as a group beneficially owned approximately 25% of our outstanding common stock. As a result, these stockholders will be able to exercise significant influence all matters requiring stockholder approval, including the election of directors, any amendment of our Certificate of Incorporation and approval of significant corporate transactions. In addition, certain of these individuals are party to the Voting Agreement, pursuant to which the parties to the Voting Agreement have the right to nominate all of the members of our board of directors and the obligation to vote for such nominees. This could have the effect of delaying or preventing a change of control or changes in management and will make the approval of certain transactions difficult without the support of these stockholders.

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

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

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

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

***Although 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 was remediated during 2021, any future material weaknesses or other inability to maintain effective internal control over financial reporting 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.

We identified a material weakness in our internal control over financial reporting related to the accounting and reporting for certain of our private warrants. Although management has concluded that this material weakness was remediated during 2021, any future material weaknesses or other inability to maintain effective internal control over financial reporting could adversely impact our ability to report our financial position and results of operations on a timely and accurate basis. If our consolidated financial statements are not accurate, investors may not have a complete understanding of our operations and may lose confidence in our financial reporting and our business, reputation, results of operations, liquidity, financial condition, stock price and ability to access the capital markets could be adversely affected. In addition, we may be unable to maintain or regain compliance with applicable securities laws, stock market listing requirements and covenants regarding the timely filing of periodic reports, we may be subject to regulatory investigations and penalties, and we may face claims invoking the federal and state securities laws. Any such litigation or dispute, whether successful or not, could have a material adverse effect on our business, results of operations and financial condition. We can provide no assurance 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.

**ITEM 5. Other Information.**

On August 10, 2022, we entered into a consulting agreement with LifeSci Consulting LLC., a global life sciences consultancy firm. Pursuant to this agreement, LifeSci Consulting will provide consulting services to us in connection with potential research, licensing and other collaboration transactions related to our product candidates and will receive a retainer of $10,000 per month and a customary success fee upon completion of a transaction. Andrew McDonald, one of our directors, is affiliated with LifeSci Consulting.

**ITEM 6. Exhibits.**

| Exhibit No. | Description |
|---|---|
| 3.1 | Second Amended and Restated Certificate of Incorporation, as amended by the Certificate of Amendment (incorporated by reference to Exhibit 3.1 to the Registration Statement on Form S-1 (File No. 333-252589) filed on January 29, 2021). |
| 3.2 | Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on April 5, 2021). |
| 31.1 | Principal Executive Officer's Certifications Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 31.2 | Principal Financial Officer's Certifications Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 32.1† | Certification Pursuant to 18 U.S.C. § 1350 (Section 906 of Sarbanes-Oxley Act of 2002). |
| 32.2† | Certification Pursuant to 18 U.S.C. § 1350 (Section 906 of Sarbanes-Oxley Act of 2002). |
| 101.INS | Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document |
| 101.SCH | Inline XBRL Taxonomy Extension Schema Document |
| 101.CAL | Inline XBRL Taxonomy Extension Calculation Linkbase Document |
| 101.DEF | Inline XBRL Taxonomy Extension Definition Linkbase Document |
| 101.LAB | Inline XBRL Taxonomy Extension Label Linkbase Document |
| 101.PRE | Inline XBRL Taxonomy Extension Presentation Linkbase Document |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

† 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 report and will not be deemed "filed" for purposes of Section 18 of the Exchange Act, or deemed to be incorporated by reference into any filing under the Exchange Act or the Securities Act, except to the extent that the registrant specifically incorporates it by reference.

## 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.**

Date: August 11, 2022

/s/ Dr. Ahmed M. Hamdy
Dr. Ahmed M. Hamdy
Chief Executive Officer

Date: August 11, 2022

/s/ Alexander A. Seelenberger
Alexander A. Seelenberger
Chief Financial Officer

**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 Quarterly Report on Form 10-Q 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: August 11, 2022

/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 Quarterly Report on Form 10-Q 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: August 11, 2022

/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 Vincerx Pharma, Inc. (the "Company"), hereby certify, that, to my knowledge:

1. The Quarterly Report on Form 10-Q for the period ended June 30, 2022 (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: August 11, 2022

/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 Vincerx Pharma, Inc. (the "Company"), hereby certify, that, to my knowledge:

1. The Quarterly Report on Form 10-Q for the period ended June 30, 2022 (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: August 11, 2022

/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.