# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**WASHINGTON, DC 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 March 31, 2022**

**OR**

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

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

**Commission File Number: 001-39333**

# Forma Therapeutics Holdings, Inc.
**(Exact Name of Registrant as Specified in its Charter)**

| **Delaware** | **37-1657129** |
|---|---|
| **(State or other jurisdiction of incorporation or organization)** | **(I.R.S. Employer Identification No.)** |
| **300 North Beacon Street, Suite 501<br>Watertown, Massachusetts** | **02472** |
| **(Address of principal executive offices)** | **(Zip Code)** |

**Registrant's telephone number, including area code: (617) 679-1970**

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

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|---|---|
| Common stock, par value $0.001 per share | FMTX | The Nasdaq Global Market |

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

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

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

| | | | |
|---|---|---|---|
| Large accelerated filer | ☒ | Accelerated filer | ☐ |
| Non-accelerated filer | ☐ | Smaller reporting company | ☐ |
| Emerging growth company | ☐ | | |

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

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

As of April 28, 2022, the registrant had 47,804,697 shares of common stock, $0.001 par value per share, outstanding.

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**Summary of the Material and Other Risks Associated with Our Business**

Our business is subject to numerous material and other risks and uncertainties that you should be aware of in evaluating our business. These risks include, but are not limited to, the following:

- We are a clinical-stage biopharmaceutical company with a limited operating history and have not generated any revenue to date from drug sales and may never become profitable.
- We have incurred significant operating losses in recent periods and anticipate that we will incur continued losses for the foreseeable future.
- We will require additional capital to finance our operations, which may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, scale back or discontinue some of our product candidate development programs or pre-commercialization efforts.
- We depend heavily on the success of our lead product candidates, etavopivat and FT-7051. We cannot be certain that we will be able to obtain regulatory approval for, or successfully commercialize, any of our current or future product candidates.
- If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.
- Rare hematologic diseases may have relatively low prevalence and it may be difficult to identify patients with the driver of the disease, which may lead to delays in enrollment for our trials.
- Business interruptions resulting from the COVID-19 global pandemic or similar public health crises could cause a disruption to the development to our product candidates and adversely impact our business.
- Our current or future product candidates may cause adverse or other undesirable side effects that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.
- If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals both for our current or future product candidates, we will not be able to commercialize, or will be delayed in commercializing, our current or future product candidates, and our ability to generate revenue will be materially impaired.
- Even if we receive regulatory approval for any of our current or future product candidates, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our current or future product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our drugs.
- Manufacturing our current or future product candidates is complex and we may encounter difficulties in production. If we encounter such difficulties, our ability to provide supply of our current or future product candidates for preclinical studies and clinical trials or for commercial purposes could be delayed or stopped.
- Even if we receive marketing approval for our current or future product candidates, our current or future product candidates may not achieve broad market acceptance, which would limit the revenue that we generate from their sales.
- We rely, and expect to continue to rely, on third parties to conduct our ongoing and planned clinical trials for our current and future product candidates. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain marketing approval for or commercialize our current and potential future product candidates and our business could be substantially harmed.
- If we are unable to obtain and maintain patent and other intellectual property protection for our technology and product candidates or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology and drugs may be impaired.

The material and other risks summarized above should be read together with the text of the full risk factors below and in the other information set forth in this Quarterly Report on Form 10-Q, including our condensed consolidated financial statements and the related notes, as well as in other documents that we file with the SEC. If any such material and other risks and uncertainties actually occur, our business, prospects, financial condition and results of operations could be materially and adversely affected. The risks summarized above or described in full below are not the only risks that we face. Additional risks and uncertainties not currently known to us, or that we currently deem to be immaterial may also materially adversely affect our business, prospects, financial condition and results of operations.

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains express or implied forward-looking statements within the meaning of the Private Securities Litigation Reform Act, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that are based on our management's belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements contained in this Quarterly Report on Form 10-Q include, but are not limited to, statements about:

- the timing and the success of preclinical studies and clinical trials of etavopivat and FT-7051 and any other product candidates, including the availability, timing and announcement of data and results of such studies and trials;
- the initiation of any clinical trials of etavopivat and FT-7051 and any other product candidates;
- our need to raise additional funding before we can expect to generate any revenues from product sales;
- our ability to conduct successful clinical trials or obtain regulatory approval for etavopivat and FT-7051 or any other product candidates that we may identify or develop;
- our heavy dependence upon the success of our research to generate and advance additional product candidates;
- our ability to establish an adequate safety and efficacy profile for etavopivat, FT-7051 or any other product candidates that we may pursue;
- the implementation of our strategic plans for our business, any product candidates we may develop and any companion diagnostics;
- our intellectual property position, including the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates any companion diagnostics;
- the rate and degree of market acceptance and clinical utility for any product candidates we may develop;
- our expectations related to estimates of our expenses, future revenues, capital requirements and our needs for additional financing;
- our ability to maintain and establish partnerships and collaborations;
- the notice of termination of certain and potential benefits from the remaining licenses to Boehringer Ingelheim International GmbH and Celgene Corporation, now Bristol-Myers Squibb Company;
- our financial performance, including our ability to obtain additional funding to fund our operation and complete further development and commercialization of our product candidates, when needed and if approved;
- our ability to effectively manage our anticipated growth;
- developments relating to our competitors and our industry, including the impact of government regulation;
- our ability to retain the continued service of our key professionals and to identify, hire and retain additional qualified professionals;
- the effect of the COVID-19 pandemic, including mitigation efforts and economic effects, on any of the foregoing or other aspects of our business operations; and
- other risks and uncertainties, including those listed under the section titled "Risk Factors."

In some cases, you can identify forward-looking statements by terminology such as "may," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "continue" or the negative of these terms or other comparable terminology. These statements are only predictions. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under the section titled "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those implied or projected by the forward-looking statements. No forward-looking statement is a guarantee of future performance. You should read this Quarterly Report on Form 10-Q and the documents that we reference in this Quarterly Report on Form 10-Q and have filed with the Securities and Exchange Commission thereto completely and with the understanding that our actual future results may be materially different from any future results expressed or implied by these forward-looking statements.

The forward-looking statements in this Quarterly Report on Form 10-Q represent our views as of the date of this Quarterly Report on Form 10-Q. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Quarterly Report on Form 10-Q.

This Quarterly Report on Form 10-Q also contains estimates, projections and other information concerning our industry, our business and the markets for our product candidates. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. Unless otherwise expressly stated, we obtained this industry, business, market, and other data from our own internal estimates and research as well as from reports, research surveys, studies, and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources. While we are not aware of any misstatements regarding any third-party information presented in this Quarterly Report on Form 10-Q, their estimates, in particular, as they relate to projections, involve numerous assumptions, are subject to risks and uncertainties and are subject to change based on various factors, including those discussed under the section titled “Risk Factors” and elsewhere in this Quarterly Report on Form 10-Q.

**Item 1. Financial Statements.**

## FORMA THERAPEUTICS HOLDINGS, INC.

### Condensed Consolidated Balance Sheets

(in thousands, except share and per share data)
**(unaudited)**

| | March 31, 2022 | December 31, 2021 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 74,415 | $ 77,421 |
| Short-term marketable securities | 346,943 | 386,805 |
| Income tax receivable | 12,050 | 11,988 |
| Prepaid expenses and other current assets | 13,117 | 10,187 |
| Total current assets | 446,525 | 486,401 |
| Property and equipment, net | 13,550 | 13,927 |
| Long-term marketable securities | 19,985 | 26,047 |
| Operating lease right-of-use asset | 21,620 | 22,074 |
| Other assets | 12,817 | 12,612 |
| Total assets | $ 514,497 | $ 561,061 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 2,044 | $ 4,145 |
| Accrued expenses and other current liabilities | 19,091 | 25,748 |
| Operating lease liability | 5,112 | 5,125 |
| Income tax payable | 90 | 70 |
| Total current liabilities | 26,337 | 35,088 |
| Operating lease liability, noncurrent | 26,967 | 27,617 |
| Total liabilities | 53,304 | 62,705 |
| Commitments and contingencies (Note 9) | | |
| Stockholders' equity: | | |
| Common stock, $0.001 par value; 150,000,000 shares authorized at March 31, 2022 and December 31, 2021; 47,771,388 and 47,411,356 shares issued at March 31, 2022 and December 31, 2021, respectively; 47,762,683 and 47,398,238 shares outstanding at March 31, 2022 and December 31, 2021, respectively | 47 | 47 |
| Preferred stock, $0.001 par value; 10,000,000 shares authorized and no issued or outstanding at March 31, 2022 and December 31, 2021 | — | — |
| Additional paid-in capital | 735,678 | 728,683 |
| Accumulated deficit | (274,532) | (230,374) |
| Total stockholders' equity | 461,193 | 498,356 |
| Total liabilities and stockholders' equity | $ 514,497 | $ 561,061 |

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

**FORMA THERAPEUTICS HOLDINGS, INC.**

## Condensed Consolidated Statements of Operations and Comprehensive Loss

(in thousands, except share and per share data)
**(unaudited)**

| | Three Months Ended March 31, | |
|---|---|---|
| | **2022** | **2021** |
| Collaboration revenue | $ — | $ — |
| Operating expenses: | | |
| Research and development | 31,273 | 26,343 |
| General and administrative | 13,136 | 9,867 |
| Total operating expenses | 44,409 | 36,210 |
| Loss from operations | (44,409) | (36,210) |
| Other income: | | |
| Interest income | 289 | 262 |
| Other expense, net | (35) | (4) |
| Total other income, net | 254 | 258 |
| Loss before taxes | (44,155) | (35,952) |
| Income tax expense | 3 | 8 |
| Net loss and comprehensive loss | $ (44,158) | $ (35,960) |
| Net loss allocable to shares of common stock, basic and diluted | $ (44,158) | $ (35,960) |
| Net loss per share of common stock, basic and diluted | $ (0.93) | $ (0.76) |
| Weighted-average shares of common stock outstanding, basic and diluted | 47,561,631 | 47,295,013 |

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

**FORMA THERAPEUTICS HOLDINGS, INC.**

## Condensed Consolidated Statements of Stockholders' Equity

(in thousands, except share data)

**(unaudited)**

| | Common Stock | | Additional Paid-In | Accumulated | Total Stockholders' |
|---|---|---|---|---|---|
| | Shares | Amount | Capital | Deficit | Equity |
| **Balance at December 31, 2020** | 47,248,685 | $ 47 | $ 705,607 | $ (57,410) | $ 648,244 |
| Exercise of options to purchase common stock | 68,389 | — | 333 | — | 333 |
| Vesting of restricted common stock | 11,501 | — | — | — | — |
| Equity-based compensation | — | — | 3,848 | — | 3,848 |
| Net loss and comprehensive loss | — | — | — | (35,960) | (35,960) |
| **Balance at March 31, 2021** | 47,328,575 | $ 47 | $ 709,788 | $ (93,370) | $ 616,465 |
| | | | | | |
| **Balance at December 31, 2021** | 47,398,238 | $ 47 | $ 728,683 | $ (230,374) | $ 498,356 |
| Exercise of options to purchase common stock | 131,788 | — | 741 | — | 741 |
| Vesting of restricted common stock | 4,413 | — | — | — | — |
| Vesting of restricted stock units | 228,244 | — | — | — | — |
| Equity-based compensation | — | — | 6,254 | — | 6,254 |
| Net loss and comprehensive loss | — | — | — | (44,158) | (44,158) |
| **Balance at March 31, 2022** | 47,762,683 | $ 47 | $ 735,678 | $ (274,532) | $ 461,193 |

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

**FORMA THERAPEUTICS HOLDINGS, INC.**

**Condensed Consolidated Statements of Cash Flows**
(in thousands)
**(unaudited)**

| | Three Months Ended March 31, | |
|---|---|---|
| | **2022** | **2021** |
| **Cash flows from operating activities** | | |
| Net loss | $ (44,158) | $ (35,960) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 638 | 183 |
| Non-cash operating lease expense | 261 | 375 |
| Equity-based compensation | 6,254 | 3,848 |
| (Accretion) amortization of marketable securities | (2) | 377 |
| Changes in operating assets and liabilities: | | |
| (Increase) decrease in income taxes receivable | (62) | 207 |
| (Increase) in prepaid expenses and other current assets | (2,930) | (1,954) |
| (Increase) in other assets | — | (2,555) |
| (Decrease) in accounts payable | (2,138) | (1,368) |
| (Decrease) in accrued expenses and other current liabilities | (6,708) | (3,990) |
| Increase in income taxes payable | 20 | 73 |
| (Decrease) in operating lease liability | (470) | (473) |
| Net cash used in operating activities | (49,295) | (41,237) |
| **Cash flows from investing activities** | | |
| Purchases of held-to-maturity marketable securities | (148,905) | (257,868) |
| Proceeds from maturity and redemption of marketable securities | 194,831 | 114,500 |
| Purchases of property and equipment | (261) | (83) |
| Net cash provided by (used in) investing activities | 45,665 | (143,451) |
| **Cash flows from financing activities** | | |
| Proceeds from exercise of options to purchase common stock | 741 | 333 |
| Payment of public offering costs | (79) | (500) |
| Net cash provided by (used in) financing activities | 662 | (167) |
| Net decrease in cash, cash equivalents and restricted cash | (2,968) | (184,855) |
| Cash, cash equivalents and restricted cash, beginning of the period | 79,538 | 285,159 |
| Cash, cash equivalents and restricted cash, end of the period | $ 76,570 | $ 100,304 |
| **Supplemental disclosure of non-cash activities:** | | |
| Operating lease right-of-use asset recognized upon adoption of Topic 842 | $ — | $ 7,478 |
| Public offering costs included in accounts payable and accrued expenses | $ 111 | $ — |

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

## Note 1—Organization and Nature of Business

Forma Therapeutics Holdings, Inc. and its wholly-owned subsidiaries, hereinafter collectively, “the Company”, is a clinical-stage biopharmaceutical company focused on the development and commercialization of novel therapeutics to transform the lives of patients with rare hematologic diseases and cancers.

On June 23, 2020, the Company completed an initial public offering (“IPO”) in which the Company issued and sold 15,964,704 shares of its common stock at a public offering price of $20.00 per share, resulting in net proceeds of $293.3 million after deducting underwriting discounts and commissions and offering expenses payable by the Company. Upon the closing of the IPO, all outstanding shares of preferred stock automatically converted into 20,349,223 shares of common stock; all issued shares of enterprise junior stock automatically converted into 2,124,845 and 103,007 shares of common stock and restricted common stock, respectively; and all outstanding warrants to purchase shares of preferred stock automatically converted into warrants to purchase an aggregate of 70,133 shares of common stock with an exercise price of $5.13 per share.

On December 15, 2020, the Company completed a follow-on public offering in which the Company issued and sold 6,095,000 shares of its common stock at a public offering price of $45.25 per share, resulting in net proceeds of $258.6 million after deducting underwriting discounts and commissions and offering expenses payable by the Company.

On July 26, 2021, the Company filed a Registration Statement on Form S-3 with the SEC, which was automatically declared effective on July 26, 2021 (File No. 333-258174), as amended by Post-Effective Amendment No. 1 and Post-Effective Amendment No. 2 on Form S-3 filed on March 1, 2022, in relation to the registration of up to $400.0 million of common stock, preferred stock, debt securities, warrants and units or any combination thereof (the “2021 Shelf”). The Company also simultaneously entered into a Sales Agreement ("Sales Agreement") with SVB Leerink LLC (the "Sales Agent") to provide for the offering, issuance and sale of up to an aggregate amount of $200.0 million of common stock from time to time in “at-the-market” offerings, with $150.0 million of common stock currently registered under the 2021 Shelf, and subject to the limitations thereof. The Company will pay to the Sales Agent cash commissions of up to 3.0% of the gross proceeds of sales of common stock under the Sales Agreement. As of the date of this Quarterly Report on Form 10-Q, the Company has not made any sales of its common stock under the Sales Agreement.

### *Liquidity*

The Company is focused on the development and commercialization of novel therapeutics to transform the lives of patients with rare hematologic diseases and cancers. The Company is building a pipeline of therapeutics with a focus on these areas and has devoted substantially all of its resources to the research and development of its drug development efforts, comprised of research and development, manufacturing, conducting clinical trials, protecting its intellectual property and general and administrative functions relating to these operations. The future success of the Company is dependent on its ability to develop its product candidates and ultimately upon its ability to attain sustained profitable operations through commercialization of products.

The Company is subject to risks common to companies in the biotechnology industry, including but not limited to, the need for additional capital, risks of failure of preclinical studies and clinical trials, the need to obtain marketing approval and reimbursement for any drug product candidate that it may identify and develop, the need to successfully commercialize and gain market acceptance of its product candidates, dependence on key personnel, protection of proprietary technology, compliance with government regulations, development of technological innovations by competitors, reliance on third-party manufacturers and the ability to transition from pilot-scale production to large-scale manufacturing of products.

The Company has determined that its cash, cash equivalents and marketable securities of $441.3 million as of March 31, 2022 will be sufficient to fund its operations for at least one year from the date these condensed consolidated financial statements are issued. To date, the Company has primarily financed its operations through license and collaboration agreements, the sale of preferred shares and preferred stock to outside investors and the completion of the IPO and follow-on public offering. The Company has experienced significant negative cash flows from operations during the three months ended March 31, 2022. The Company does not expect to experience any significant positive cash flows from its existing collaboration agreements and does not expect to have any product revenue in the near term. The Company expects to incur substantial operating losses and negative cash flows from operations for the foreseeable future as it continues to invest significantly in research and development of its programs. Management's belief with respect to its ability to fund operations is based on estimates that are subject to risks and uncertainties. If actual results are different from management's estimates, the Company may need to seek additional funding sooner than would otherwise be expected. There can be no assurance that the Company will be able to obtain additional funding on acceptable terms, if at all.

**Note 2—Summary of Significant Accounting Policies**

***Basis of Presentation and Consolidation***

The condensed consolidated financial statements include the accounts of Forma Therapeutics Holdings, Inc. and its wholly owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

The Company has prepared the accompanying condensed consolidated financial statements in conformity with accounting principles generally accepted in the United States of America ("GAAP") and pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC"). Certain information and footnote disclosures generally included in financial statements in conformity with GAAP have been condensed or omitted in accordance with such rules and regulations. Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standard Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

***Significant Accounting Policies***

These condensed consolidated financial statements should be read in conjunction with the Company's consolidated financial statements and the notes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2021.

***Unaudited Interim Condensed Consolidated Financial Statements***

The accompanying condensed consolidated balance sheet as of March 31, 2022, the condensed consolidated statements of operations and comprehensive loss for the three months ended March 31, 2022 and 2021, the condensed consolidated statements of stockholders' equity for the three months ended March 31, 2022 and 2021 and the condensed consolidated statements of cash flows for the three months ended March 31, 2022 and 2021 are unaudited. The financial data and other information contained in the notes thereto as of March 31, 2022 and for the three months ended March 31, 2022 and 2021 are also unaudited. The condensed consolidated balance sheet data as of December 31, 2021 was derived from the Company's audited consolidated financial statements included in the Annual Report on Form 10-K for the fiscal year ended December 31, 2021.

The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements as of and for the year ended December 31, 2021, and in the opinion of the Company's management, reflect all adjustments which are necessary to present fairly the Company's financial position as of March 31, 2022, the results of its operations for the three months ended March 31, 2022 and 2021 and cash flows for the three months ended March 31, 2022 and 2021. Such adjustments are of a normal and recurring nature. These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements as of and for the year ended December 31, 2021, and the notes thereto, included in the Annual Report on Form 10-K for the fiscal year ended December 31, 2021.

***Cash, Cash Equivalents and Restricted Cash***

The Company considers all short-term, highly liquid investments with original maturities of 90 days or less at acquisition date to be cash equivalents. The carrying amounts of the Company's cash equivalents approximate their fair value due to their short-term nature.

Amounts in restricted cash consist of letters of credit and a security deposit to secure the Company's facilities. Restricted cash is included in other assets on the condensed consolidated balance sheets. The following table reconciles cash, cash equivalents and restricted cash as of March 31, 2022 and 2021 to the condensed consolidated statements of cash flows (in thousands):

| | March 31, | |
|---|---|---|
| | 2022 | 2021 |
| Cash and cash equivalents | $ 74,415 | $ 97,834 |
| Restricted cash | 2,155 | 2,470 |
| Total cash, cash equivalents and restricted cash as shown in the condensed consolidated statements of cash flows | $ 76,570 | $ 100,304 |

***Marketable Securities***

Marketable securities generally consist of U.S. Treasury securities, debt securities of U.S. Government agencies and corporate entities and commercial paper. The objectives for holding investments are to invest the Company's excess cash resources in investment vehicles that provide a better rate of return compared to an interest-bearing bank account with limited risk to the principal invested. Marketable securities with original maturities of greater than 90 days and remaining maturities of less than one year from the balance sheet date are classified as short-term marketable securities. Marketable securities with remaining maturities of greater than one year from the balance sheet date are classified as long-term marketable securities. All investments are classified as held-to-maturity marketable securities as the Company does not have intent to sell these securities and it is more likely than not the Company will not be required to sell such investments before recovery of their amortized cost basis. Held-to-maturity securities are stated at their amortized cost, adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion is included in interest income in the condensed consolidated statements of operations and comprehensive loss.

***Comprehensive Loss***

Comprehensive loss includes net loss as well as other changes in stockholders' equity that result from transactions and economic events other than those with the equity holders. There was no difference between net loss and comprehensive loss presented in the accompanying condensed consolidated financial statements for the three months ended March 31, 2022 and 2021.

***Recently Issued Accounting Pronouncements***

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments—Credit Losses (Topic 326)—Measurement of Credit Losses on Financial Instruments, which has been subsequently amended by ASU No. 2018-19, ASU No. 2019-04, ASU No. 2019-05, ASU No. 2019-10, ASU No. 2019-11, ASU No. 2020-02 and ASU No. 2022-02 ("ASU 2016-13"). The provisions of ASU 2016-13 modify the impairment model to utilize an expected loss methodology in place of the currently used incurred loss methodology and require a consideration of a broader range of reasonable and supportable information to inform credit loss estimates. Although earlier adoption is permitted, the Company plans to adopt ASU 2016-13 on January 1, 2023. The Company is currently evaluating the potential impact that this standard may have on its condensed consolidated financial statements and related disclosures.

**Note 3—Fair Value of Financial Assets**

The following tables present information about the Company's assets that are measured or disclosed at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values (in thousands):

| | | Fair Value Measurements at the Reporting Date Using | | |
|---|---|---|---|---|
| | March 31, 2022 | Quoted Prices In Active Markets Using Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) |
| **Assets—Cash equivalents** | | | | |
| Repurchase agreement | $ 25,000 | $ — | $ 25,000 | $ — |
| Money market funds | 45,736 | 45,736 | — | — |
| **Assets—Short-term marketable securities** | | | | |
| U.S. Government agency securities | 39,927 | — | 39,927 | — |
| U.S. Treasury securities | 54,881 | 54,881 | — | — |
| Commercial paper | 217,008 | — | 217,008 | — |
| Corporate debt securities | 33,969 | — | 33,969 | — |
| **Assets—Long-term marketable securities** | | | | |
| U.S. Treasury securities | 19,665 | 19,665 | — | — |
| Total | $ 436,186 | $ 120,282 | $ 315,904 | $ — |

| | | Fair Value Measurements at the Reporting Date Using | | |
|---|---|---|---|---|
| | December 31, 2021 | Quoted Prices In Active Markets Using Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) |
| **Assets—Cash equivalents** | | | | |
| Repurchase agreement | $ 25,000 | $ — | $ 25,000 | $ — |
| Money market funds | 49,957 | 49,957 | — | — |
| **Assets—Short-term marketable securities** | | | | |
| U.S. Government agency securities | 40,022 | — | 40,022 | — |
| U.S. Treasury securities | 27,972 | 27,972 | — | — |
| Commercial paper | 268,472 | — | 268,472 | — |
| Corporate debt securities | 50,271 | — | 50,271 | — |
| **Assets—Long-term marketable securities** | | | | |
| U.S. Government agency securities | 1,991 | — | 1,991 | — |
| U.S. Treasury securities | 23,958 | 23,958 | — | — |
| Total | $ 487,643 | $ 101,887 | $ 385,756 | $ — |

During the three months ended March 31, 2022 and twelve months ended December 31, 2021 there were no transfers into or out of Level 3.

The Company's Level 2 investments classified as cash equivalents and marketable securities are valued using third-party pricing sources. The pricing services utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities, issuer credit spreads, benchmark securities and other observable inputs.

**Note 4—Marketable Securities**

The following table presents the carrying amounts and estimated fair values of financial instruments not measured at fair value in the condensed consolidated balance sheets as they are considered held-to-maturity securities.

The Company's investments by type consisted of the following (in thousands):

| | March 31, 2022 | | | |
|---|---|---|---|---|
| | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Estimated Fair Value |
| **Assets** | | | | |
| U.S. Government agency securities | $ 39,999 | $ — | $ (72) | $ 39,927 |
| U.S. Treasury securities | 75,079 | — | (533) | 74,546 |
| Commercial paper | 217,695 | — | (687) | 217,008 |
| Corporate debt securities | 34,155 | — | (186) | 33,969 |
| Total | $ 366,928 | $ — | $ (1,478) | $ 365,450 |

| | December 31, 2021 | | | |
|---|---|---|---|---|
| | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Estimated Fair Value |
| **Assets** | | | | |
| U.S. Government agency securities | $ 42,032 | $ — | $ (19) | $ 42,013 |
| U.S. Treasury securities | 52,048 | — | (118) | 51,930 |
| Commercial paper | 268,471 | 38 | (37) | 268,472 |
| Corporate debt securities | 50,301 | — | (30) | 50,271 |
| Total | $ 412,852 | $ 38 | $ (204) | $ 412,686 |

As marketable securities are considered held-to-maturity, the unrealized gains and losses are not recorded within the condensed consolidated financial statements.

As of March 31, 2022 and December 31, 2021, the Company held 52 and 34 investments, respectively, in an unrealized loss position with an aggregate fair value of $365.5 million and $219.3 million, respectively. These investments were in a loss position for less than 12 months and the Company considered the loss to be temporary in nature. The Company considered the decline in market value for these investments to be primarily attributable to economic and market conditions. The aggregate of individual unrealized losses as of March 31, 2022 and December 31, 2021 was not significant.

**Note 5—Prepaid Expenses and Other Current Assets**

Prepaid expenses and other current assets consisted of the following (in thousands):

| | March 31, 2022 | December 31, 2021 |
|---|---|---|
| Manufacturing and clinical prepaid expenses | $ 7,451 | $ 5,559 |
| Other prepaid expenses | 3,967 | 3,549 |
| Other non-trade receivables | 1,699 | 1,079 |
| Total | $ 13,117 | $ 10,187 |

**Note 6—Property and Equipment, Net**

Property and equipment, net consisted of the following (in thousands):

| | March 31, 2022 | December 31, 2021 |
|---|---|---|
| Computer and office equipment | $ 1,676 | $ 1,593 |
| Software | 388 | 388 |
| Lab equipment | 1,899 | 1,906 |
| Furniture and fixtures | 1,301 | 1,248 |
| Leasehold improvements | 13,413 | 13,386 |
| Construction in process | 108 | 175 |
| Total | 18,785 | 18,696 |
| Less: Accumulated depreciation | (5,235) | (4,769) |
| Total | $ 13,550 | $ 13,927 |

Depreciation and amortization expense related to property and equipment for the three months ended March 31, 2022 and 2021 totaled $0.6 million and $0.2 million, respectively.

**Note 7—Leases**

In January 2022, the Company entered into a lease for office space in Burlingame, CA (the “Chapin Avenue Lease”). The Chapin Avenue Lease is subject to base rent of $0.1 million per month, plus the Company's ratable share of taxes, maintenance and other operating expenses. Base rent is subject to a 3.0% annual increase over the 4-year, 4-month lease term. The Company is not obligated to pay base rent for the first four months following lease commencement. In addition, the Chapin Avenue Lease provides an extension option for one additional three-year term at then-market rates. The Company paid first month’s rent of $0.1 million upon execution of the Chapin Avenue Lease agreement and a security deposit of $0.1 million, which are classified in prepaid expenses and other current assets and other assets on the condensed consolidated balance sheet, respectively. No further rent or operating expenses are owed until the Company takes occupancy at the contractual commencement date, which is currently anticipated to be in late June 2022. Upon the accounting commencement date, which is expected to coincide with the date the Company takes occupancy of the premises, the Company will assess the classification of the Chapin Avenue Lease and measure the associated lease liability and right-of-use asset that will be recognized. Additionally, the prepaid rent will be reclassified as an increase in the right-of-use asset.

**Note 8—Accrued Expenses and Other Current Liabilities**

Accrued expenses and other current liabilities consisted of the following (in thousands):

| | March 31, 2022 | December 31, 2021 |
|---|---|---|
| Manufacturing and clinical accruals | $ 9,382 | $ 11,001 |
| Employee compensation | 4,503 | 8,508 |
| Other research and development related accruals | 2,867 | 3,804 |
| Professional and consulting services | 1,144 | 971 |
| Other current liabilities | 1,195 | 1,464 |
| Total | $ 19,091 | $ 25,748 |

**Note 9—Commitments and Contingencies**

***Guarantees and Indemnification Obligations***

The Company enters into standard indemnification agreements in the ordinary course of business. Pursuant to these agreements, the Company indemnifies and agrees to reimburse the indemnified party for losses and costs incurred by the indemnified party, generally the Company’s customers, in connection with any patent, copyright, trade secret or other intellectual property or personal right infringement claim by any third party with respect to the Company’s technology. The term of these indemnification agreements is generally perpetual after execution of the agreement. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is unlimited. Based on historical experience and information known as of March 31, 2022 and December 31, 2021, the Company had not incurred any costs for the above guarantees and indemnities.

**Note 10—Stockholders' Equity**

*Common Stock Reserved for Future Issuances*

As of March 31, 2022, the Company had reserved for future issuance the following number of shares of common stock:

| | Number of Shares Reserved |
|---|---|
| For exercise of stock options under the 2019 Stock Incentive Plan | 3,645,709 |
| For exercise of stock options under the 2020 Stock Option and Incentive Plan | 2,995,875 |
| For restricted stock units granted under the 2020 Stock Option and Incentive Plan | 1,618,779 |
| For future issuance under the 2020 Stock Option and Incentive Plan | 2,604,681 |
| For future issuance under the 2020 Employee Stock Purchase Plan | 1,314,014 |
| Total | 12,179,058 |

**Note 11—Equity-Based Compensation**

***2020 Stock Option and Incentive Plan***

The Company grants stock-based awards under the 2020 Stock Option and Incentive Plan (the "2020 Plan"). The Company also has stock options and restricted common stock outstanding under the 2019 Stock Incentive Plan (the "2019 Plan") and 2012 Equity Incentive Plan, as Amended and Restated, (the "2012 Plan") respectively, but is no longer granting awards under such plans. All shares of common stock underlying any awards that are forfeited, cancelled, expired, repurchased, or otherwise terminated under the 2020 and 2019 Plans are added back to the shares of common stock available for issuance under the 2020 Plan, while all unvested shares under the 2012 Plan that are forfeited, cancelled or are otherwise terminated that are reserved under the 2012 Plan are automatically retired. On January 1, 2022, the number of shares of common stock available for issuance under the 2020 Plan increased by 1,896,454 shares as a result of the automatic increase provision of the 2020 Plan. As of March 31, 2022, there were 2,604,681 shares available for future issuance under the 2020 Plan.

***Equity-Based Compensation Expense***

Equity-based compensation expense was as follows (in thousands):

| | Three Months Ended March 31, | |
|---|---|---|
| | 2022 | 2021 |
| Research and development | $ 2,711 | $ 1,455 |
| General and administrative | 3,543 | 2,393 |
| Total | $ 6,254 | $ 3,848 |
| | | |
| Restricted common stock | $ 25 | $ 100 |
| Restricted stock units | 2,549 | 1,050 |
| Stock options | 3,680 | 2,698 |
| Total | $ 6,254 | $ 3,848 |

***Stock Options***

The following table summarizes the Company's stock option activity under the 2019 and 2020 Plans:

| | Number of Shares | Weighted Average Exercise Price Per share | Weighted Average Remaining Contractual Term | Aggregate Intrinsic Value |
|---|---|---|---|---|
| | | | (in years) | (in thousands) |
| Outstanding as of December 31, 2021 | 5,942,569 | $ 14.12 | 8.1 | $ 33,891 |
| Granted | 881,690 | 10.08 | | |
| Exercised | (131,788) | 5.25 | | |
| Forfeited | (50,887) | 25.17 | | |
| Outstanding as of March 31, 2022 | 6,641,584 | $ 13.69 | 8.3 | $ 14,696 |
| Exercisable as of March 31, 2022 | 2,827,068 | $ 10.87 | 7.7 | $ 8,709 |
| Vested and expected to vest as of March 31, 2022 | 6,641,584 | $ 13.69 | 8.3 | $ 14,696 |

The weighted-average grant date fair value per share of stock options granted during the three months ended March 31, 2022 and 2021 was $6.98 and $25.68, respectively. The aggregate intrinsic value of stock options exercised during the three months ended March 31, 2022 and 2021 was $0.7 million and $2.3 million, respectively.

As of March 31, 2022, there was approximately $38.0 million of unrecognized equity-based compensation expense related to stock options that is expected to be recognized over a weighted-average period of approximately 2.6 years.

*Stock Options Valuation*

The following assumptions were used in determining the fair value of stock options presented on a weighted average basis:

| | Three Months Ended March 31, | |
|---|---|---|
| | 2022 | 2021 |
| Risk-free interest rate | 1.80% | 0.94% |
| Expected term (in years) | 6.1 | 6.1 |
| Expected volatility | 79.8% | 78.0% |
| Expected dividend yield | 0.0% | 0.0% |

***Restricted Stock Units***

The following table summarizes the Company's restricted stock unit activity under the 2020 Plan:

| | Number of Shares | Weighted Average Grant Date Fair Value |
|---|---|---|
| Unvested as of December 31, 2021 | 817,704 | $ 33.31 |
| Granted | 1,051,197 | $ 9.92 |
| Vested | (228,244) | $ 38.32 |
| Forfeited | (21,878) | $ 22.80 |
| Unvested as of March 31, 2022 | 1,618,779 | $ 17.56 |

The aggregate fair value of restricted stock units that vested during the three months ended March 31, 2022 was $8.8 million. The weighted-average grant date fair value of restricted stock units granted during the three months ended March 31, 2021 was $38.24 per share.

As of March 31, 2022, there was approximately $26.2 million of unrecognized equity-based compensation expense related to the restricted stock units that is expected to be recognized over a weighted-average period of approximately 3.3 years.

***Restricted Common Stock***

The following table summarizes the Company's restricted common stock activity under the 2012 Plan:

| | Number of Shares | Weighted Average Grant Date Fair Value |
|---|---|---|
| Issued and unvested as of December 31, 2021 | 13,118 | $ 4.11 |
| Vested | (4,413) | $ 5.98 |
| Forfeited | — | $ — |
| Issued and unvested as of March 31, 2022 | 8,705 | $ 3.17 |

The aggregate fair value of restricted common stock that vested during the three months ended March 31, 2022 and 2021 was $0.1 million and $0.1 million, respectively.

As of March 31, 2022, there was approximately $0.1 million of unrecognized equity-based compensation expense related to the restricted common stock that is expected to be recognized over a weighted-average period of less than one year.

***2020 Employee Stock Purchase Plan***

The 2020 Employee Stock Purchase Plan ("ESPP") became effective June 2020. On January 1, 2022, the number of shares of common stock available for issuance under the ESPP increased by 473,982 shares as a result of the automatic increase provision of the ESPP. As of March 31, 2022, no shares have been issued under the ESPP and 1,314,014 shares remain available for issuance.

**Note 12—Net Loss per Share**

The following table sets forth the outstanding shares of common stock equivalents, presented based on amounts outstanding at each period end, which were excluded from the calculation of diluted net loss per share for the periods indicated because including them would have had an anti-dilutive effect:

| | Three Months Ended March 31, | |
|---|---|---|
| | 2022 | 2021 |
| Stock options | 6,641,584 | 5,856,426 |
| Restricted common stock | 8,705 | 37,966 |
| Restricted stock units | 1,618,779 | 630,160 |

**Note 13—Income Taxes**

Income taxes for the three months ended March 31, 2022 and 2021 have been calculated based on an estimated annual effective tax rate and certain discrete items. For the three months ended March 31, 2022 and 2021, the Company recorded an insignificant income tax expense. The Company's income tax expense for the three months ended March 31, 2022 and 2021 related to state tax expense generated against investment income.

**Note 14—Equity Investment**

The Company holds a preferred share equity investment in Valo Health, Inc. ("Valo Health") which the Company received, among other consideration, in connection with the Company's divesture of select hit discovery capabilities to Valo Health during the year ended December 31, 2020. As the preferred shares do not have a readily determinable fair value and the Company does not have a significant influence on the operating and financial policies of Valo Health, the Company accounted for its equity investment in Valo Health by applying the measurement alternative under ASC 321, Equity Securities ("ASC 321"). As of March 31, 2022, no impairments, nor any upward or downward adjustments have been recognized on the equity investment in Valo Health as there have been no observable price changes. The carrying value of the Company's equity investment in Valo Health, which is classified in other assets in the condensed consolidated balance sheets, was equal to $10.0 million as of March 31, 2022 and December 31, 2021.

**Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.**

*The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, filed with the Securities and Exchange Commission, or the SEC, on March 1, 2022. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Quarterly Report on Form 10-Q, our actual results could differ materially from the results described in, or implied by, the forward-looking statements contained in the following discussion and analysis.*

**Overview**

We are a clinical-stage biopharmaceutical company focused on the development and commercialization of novel therapeutics to transform the lives of patients with rare hematologic diseases and cancers. Our drug discovery expertise has generated a pipeline of product candidates focused on indications with significant unmet patient need. Our pipeline consists of four product candidates, two of which we are pursuing for our development, etavopivat for the treatment of sickle cell disease, or SCD, and other hemoglobinopathies, and FT-7051 for the treatment of metastatic castration-resistant prostate cancer, or mCRPC.

Our lead product candidate, etavopivat, is a novel, oral, once-daily, potentially disease-modifying therapy initially being studied for the treatment of SCD. SCD, one of the most common single-gene disorders in the world, is a chronic hemolytic anemia that affects hemoglobin, the iron-containing protein in red blood cells, or RBCs, that delivers oxygen to cells throughout the body. SCD is often characterized by low hemoglobin levels, painful vaso-occlusive crises, or VOCs, progressive multi-organ damage and early death. Etavopivat is a potent activator of pyruvate kinase-R, or PKR, designed to improve RBC metabolism, function and survival, and potentially resulting in both increased hemoglobin levels and reduced VOCs. We have completed our evaluation of etavopivat in a multi-center, placebo-controlled Phase I trial in SCD patients ages 12 years and older. Based on the results of the Phase I trial, we opened a global pivotal Phase II/III trial, which we refer to as the Hibiscus Study, in SCD patients in late 2020 and began enrolling patients in the first quarter of 2021. In June 2021, we announced initial data from our 12-week open-label extension, or OLE, cohort of our Phase I trial studying effects of the 400 mg of etavopivat once-daily on SCD patients and provided updated results in December 2021. We have initiated a Phase II trial in patients with either transfusion dependent SCD, transfusion dependent thalassemia, or non-transfusion dependent thalassemia. We have received Fast Track, Rare Pediatric Disease and Orphan Drug designations from the U.S. Food and Drug Administration, or FDA, for etavopivat in SCD patients. The European Medicines Agency has granted Orphan Drug designation to etavopivat for the treatment of SCD.

Our product candidate, FT-7051, is a potent and selective inhibitor of CREB-binding protein/E1A binding protein p300, or CBP/p300, in clinical development for the treatment of mCRPC. Prostate cancer is reported as the second and third leading cause of cancer death for men in the United States and in Europe, respectively, and mCRPC is the most advanced form of the disease. Prostate cancer cell growth is driven by activity of the androgen receptor. Virtually all patients with advanced disease who demonstrate initial clinical responses to current treatments eventually acquire resistance to these agents. Third party studies have shown that approximately 20% to 40% of mCRPC patients who develop resistance express an androgen receptor, or AR, splice variant called AR-v7. Studies have demonstrated that CBP/p300 is a co-activator of the AR, and, therefore, we believe that inhibiting CBP/p300 may play an important role in the suppression of mCRPC in patients having AR resistant variants. The FDA cleared our investigational new drug application, or IND, for FT-7051 in April 2020, and we dosed the first patient in our Phase I trial, which we refer to as the Courage Study, in mCRPC patients in January 2021. In October 2021, initial results from eight patients in this Phase I trial were presented at the AACR-NCI-EORTC Virtual International Conference on Molecular Targets and Cancer Therapeutics.

We continue to plan to pursue a strategic partner for the further development and potential commercialization of our compound, olutasidenib, a selective inhibitor of mutant isocitrate dehydrogenase 1, or mIDH1. IDH1 mutations have been shown to be oncogenic for patients with acute myeloid leukemia, or AML, and glioma. We have successfully completed a registrational Phase II trial for olutasidenib in relapsed / refractory acute myeloid leukemia, or R/R AML. In December 2021, we presented the first Phase II results of olutasidenib used in combination with azacitidine at the American Society of Hematology (ASH) Annual Meeting. We are progressing a new drug application, or NDA, for the treatment of R/R AML. We are also completing our exploratory Phase I clinical trial for olutasidenib in glioma.

Additionally, we licensed exclusively two programs each to Boehringer Ingelheim International GmbH, or Boehringer Ingelheim, and Celgene Corporation, now Bristol-Myers Squibb Company, or Bristol-Myers Squibb, based on molecules

that we discovered. In May and July 2021, we received written notice from Bristol-Myers Squibb and Boehringer Ingelheim, respectively, of their termination of one of these licensed programs each. Under the remaining out-licensed programs we are eligible to receive potential clinical and commercial milestone payments plus royalties over time.

**COVID-19 Pandemic**

The ultimate extent of the ongoing impact of the COVID-19 global pandemic on our business, financial condition and results of operations is highly uncertain and will depend on future developments that cannot be predicted, including new information that may emerge concerning the severity of the COVID-19 pandemic, the impact of new strains of COVID-19, the effectiveness, availability and utilization of vaccines, and actions taken by government authorities and businesses to contain or prevent the further spread of COVID-19. For instance, a recurrence of COVID-19 cases or the impact of new variants of the virus could cause a more widespread or severe impact on commercial activity depending on where infection rates are highest. If we or any of the third parties with whom we engage, were to experience any additional shutdowns or other prolonged business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially or negatively affected, which could have a material adverse impact on our business, results of operations and financial condition. To date, many clinical trials, including ours, have been impacted by the COVID-19 pandemic, with clinical trial sites implementing new policies in response to the COVID-19 pandemic, resulting in potential delays to enrollment of clinical trials or changes in the ability to access sites participating in clinical trials. The ongoing COVID-19 pandemic has impacted patients' visits to study sites for both our etavopivat and olutasidenib programs. We continue to work closely with our contract research organizations, or CROs, and the study sites to ensure patient safety and help facilitate study conduct. We will continue to monitor developments as we address the disruptions and uncertainties relating to the COVID-19 pandemic.

**Financial Operations Overview**

***Revenue***

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from the sale of products in the foreseeable future. Historically, our revenue has been primarily derived from collaboration agreements to discover, develop, and commercialize drug candidates. Our collaboration arrangements with Celgene Corporation were all terminated in December 2018, upon which we entered into a worldwide license agreement with Celgene Corporation, now Bristol-Myers Squibb, for FT-1101 and USP30 which were delivered during the year ended December 31, 2019. In May 2021 we received written notice from Bristol-Myers Squibb of their termination of the license agreement related to FT-1101. In July 2021 we received written notice from Boehringer Ingelheim of their termination of the license related to our protein modulator molecule. We expect revenue for the next several years will be derived primarily from milestone payments under our remaining license agreements with Bristol-Myers Squibb and Boehringer Ingelheim, if Bristol-Myers Squibb or Boehringer Ingelheim achieve certain specified commercial, development and regulatory milestones in their ongoing development of our licensed compounds and potential royalties upon future sales of these licensed compounds, as well as other collaboration and license agreements that we may enter in the future, if any. We have not recognized any revenue in the three months ended March 31, 2022 and 2021.

***Operating Expenses***

*Research and Development Expense*

Research and development expense consists of expenses incurred in connection with the discovery and development of our product candidates, including the conduct of preclinical and clinical studies and product development, which are expensed as they are incurred. These expenses consist primarily of:

- compensation, benefits, including equity-based compensation, and other employee related expenses;
- research and development related facility and depreciation costs;
- supplies to support our internal research and development efforts; and

- third-party contract costs relating to research, process and formulation development, preclinical and clinical studies and regulatory operations.

We track direct research and development expenses, consisting principally of external costs, such as costs associated with CROs and manufacturing of preclinical and clinical drug product and other outsourced research and development expenses to specific product programs once a product candidate has been selected. We do not allocate internal research and development expenses consisting of employee and contractor-related costs, costs associated with our research and facility expenses, including depreciation or other indirect costs, to specific product candidate programs because these costs are deployed across multiple product candidate programs under research and development and, as such, are separately classified. The table below summarizes our research and development direct expenses for non-partnered product candidates and both external and internal costs for partnered programs and those costs that were unallocated to programs for the periods presented (in thousands):

| | Three Months Ended March 31, | |
|---|---|---|
| | 2022 | 2021 |
| Etavopivat | $ 8,638 | $ 9,794 |
| FT-7051 | 1,486 | 969 |
| Olutasidenib | 3,397 | 3,963 |
| External predevelopment and unallocated expenses | 2,232 | 2,531 |
| Internal research and development expenses | 15,520 | 9,086 |
| Total | $ 31,273 | $ 26,343 |

We invest carefully in our pipeline, and the commitment of funding for each subsequent stage of our development programs is dependent upon the receipt of clear, supportive data. We anticipate that we will make determinations as to which additional programs to pursue and how much funding to direct to each program on an ongoing basis in response to the scientific and clinical data of each product candidate, as well as the competitive landscape and ongoing assessments of such product candidate's commercial potential. We expect our research and development costs will be substantial for the foreseeable future. We expect costs associated with our etavopivat and FT-7051 programs to increase as the programs progress through clinical development. We expect costs associated with olutasidenib to decrease over time, as the ongoing clinical trials for olutasidenib in AML and solid tumors progress towards completion.

At this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the development of, and obtain regulatory approval for, any of our product candidates. This is due to the numerous risks and uncertainties associated with drug development, including the uncertainty of:

- our ability to add and retain key research, pharmaceutical sciences and development personnel;
- our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize etavopivat and FT-7051;
- our successful enrollment in and completion of clinical trials, including our ability to generate positive data from any such clinical trials;
- the costs associated with the development of any additional development programs we identify in-house or acquire through collaborations or other arrangements;
- our ability to discover, develop and utilize biomarkers to demonstrate target engagement, pathway engagement and the impact on disease progression, as applicable, of our product candidates;
- our ability to establish and maintain agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing;
- our ability to forecast and meet supply requirements for clinical trials and commercialized products using third-party manufacturers;
- the terms and timing of any additional partnership, collaboration, license or other arrangement, including the terms and timing of any payments thereunder;
- the ability to develop and obtain clearance or approval of companion diagnostic tests, if required, on a timely basis, or at all;
- obtaining and maintaining third-party coverage and adequate reimbursement, if etavopivat or FT-7051 is approved;
- acceptance of our lead product candidates, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies, if etavopivat or FT-7051 is approved;
- our ability to obtain and maintain patent, trade secret and other intellectual property protection for etavopivat and FT-7051 and regulatory exclusivity for etavopivat and FT-7051 if and when approved;

- our receipt of marketing approvals for etavopivat and FT-7051 from applicable regulatory authorities; and
- the continued acceptable safety profiles of our lead products following approval.

A change in any of these variables with respect to any of our programs would significantly change the costs, timing and viability associated with that program.

*General and Administrative Expense*

General and administrative expense consists primarily of salaries and other related costs, including equity-based compensation, for personnel in our executive, finance, legal, business development and administrative functions. General and administrative expenses also include legal fees relating to patent and corporate matters; professional fees for accounting, auditing, tax and administrative consulting services; insurance costs; administrative travel expenses; and facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs. These costs relate to the operation of the business, unrelated to the research and development function, or any individual program.

Our general and administrative expenses may increase in the future as our organization and headcount needed to support our research and development activities grows and the potential commercialization of our product candidates, if approved. We also expect to incur increased expenses associated with being a public company, including increased costs of accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and Securities Exchange Commission, or SEC, requirements, director and officer insurance costs, and investor and public relations costs. We also expect to incur additional intellectual property-related expenses as we file patent applications to protect innovations arising from our research and development activities.

***Interest Income***

Interest income consists of interest generated from our cash, cash equivalents and marketable securities and amortization and accretion of purchase premiums and discounts associated with our investments.

***Other Expense, Net***

Other expense, net primarily consists of gains and losses recognized from the revaluation of foreign exchange rates due to timing of payments made on accounts payable.

***Income Taxes***

Income tax expense is comprised of domestic (US federal and state) income taxes at the applicable tax rates adjusted for non-deductible expenses, research and development tax credits, and other permanent differences. Our income tax provision may be significantly affected by changes to our estimates. However, due to the full valuation allowance on our deferred tax assets, the net impact to our overall income tax expense is zero.

**Results of Operations**

***Comparison of the Three Months Ended March 31, 2022 and 2021***

The following table summarizes our condensed consolidated statements of operations for each period presented (in thousands):

| | Three Months Ended March 31, | | Change |
|---|---|---|---|
| | 2022 | 2021 | ($) |
| Collaboration revenue | $ — | $ — | $ — |
| Operating expenses: | | | |
| Research and development | 31,273 | 26,343 | 4,930 |
| General and administrative | 13,136 | 9,867 | 3,269 |
| Total operating expenses | 44,409 | 36,210 | 8,199 |
| Loss from operations | (44,409) | (36,210) | (8,199) |
| Other income: | | | |
| Interest income | 289 | 262 | 27 |
| Other expense, net | (35) | (4) | (31) |
| Total other income, net | 254 | 258 | (4) |
| Loss before taxes | (44,155) | (35,952) | (8,203) |
| Income tax expense | 3 | 8 | (5) |
| Net loss | $ (44,158) | $ (35,960) | $ (8,198) |

*Collaboration Revenue*

There was no collaboration revenue for the three months ended March 31, 2022 and 2021.

*Research and Development Expense*

The following table summarizes our research and development expenses for each period presented (in thousands):

| | Three Months Ended March 31, | | Change |
|---|---|---|---|
| | 2022 | 2021 | ($) |
| Etavopivat | $ 8,638 | $ 9,794 | $ (1,156) |
| FT-7051 | 1,486 | 969 | 517 |
| Olutasidenib | 3,397 | 3,963 | (566) |
| External predevelopment and unallocated expenses | 2,232 | 2,531 | (299) |
| Internal research and development expenses | 15,520 | 9,086 | 6,434 |
| Total research and development expense | $ 31,273 | $ 26,343 | $ 4,930 |

Research and development expense increased by $4.9 million from $26.3 million for the three months ended March 31, 2021 to $31.3 million for the three months ended March 31, 2022.

The increase in research and development expense was primarily attributable to a $6.4 million increase in internal research and development expenses due to an increase in research and development staff to support advancement of our etavopivat and other programs, an increase in equity-based compensation, and an increase of $0.5 million for FT-7051 program due to progression of our Phase I clinical trial, offset by a $0.3 million decrease in external predevelopment and unallocated expenses predominately related to the timing of investment in our preclinical programs, a $1.2 million decrease in etavopivat driven by contract manufacturing organization, or CMO, costs related to completion of registrational batches manufacturing, and a decrease of $0.6 million for olutasidenib as the studies advance toward completion.

*General and Administrative Expense*

General and administrative expense increased by approximately $3.3 million to $13.1 million for the three months ended March 31, 2022 from $9.9 million for the three months ended March 31, 2021.

The increase in general and administrative expense was primarily attributable to a $1.2 million increase in equity-based compensation, a $1.6 million increase in personnel-related costs due to executive and staff hiring, recruiting and relocation costs and a $0.5 million increase in other general and administrative costs.

**Liquidity and Capital Resources**

***Sources of Liquidity***

To date, we have financed our operations primarily with proceeds from our license and collaboration agreements, through the issuance and sale of our preferred shares and preferred stock to outside investors and completion of our initial public offering, or IPO, and follow-on public offering. From inception through March 31, 2022, we have raised an aggregate of $144.0 million in gross proceeds from sales of our preferred shares and preferred stock, $551.9 million in net proceeds from the sale of our common stock, and approximately $895.8 million in proceeds from our collaboration arrangements with third parties. As of March 31, 2022, we had cash, cash equivalents and marketable securities of $441.3 million.

In addition, in July 2021, we entered into a Sales Agreement with SVB Leerink LLC to provide for the offering, issuance and sale of up to an aggregate amount of $200.0 million of common stock from time to time in "at-the-market" offerings, with $150.0 million of common stock currently registered under a Registration Statement on Form S-3 (as amended), and subject to the limitations thereof. As of the date of this Quarterly Report on Form 10-Q, we have not made any sales of our common stock under the Sales Agreement.

Continued cash generation is highly dependent on our ability to establish new third-party collaborators, through out-licensing of assets and from potential milestones from existing out-licensed programs with Bristol-Myers Squibb and Boehringer Ingelheim, in addition to our ability to finance our operations through a combination of equity offerings, debt financings, collaboration arrangements and strategic transactions. Although we have been profitable in prior years, due to our significant research and development expenditures and the termination of certain collaboration arrangements, we have experienced periods of negative cash flows from operations, even in periods of operating income. For the three months ended March 31, 2022 we experienced a loss from operations and negative cash flows from operations. We anticipate incurring operating losses and negative cash flows from operations for the foreseeable future, particularly as we move forward with our clinical-stage programs. We do not expect to generate revenue from product sales for several years, if at all.

***Cash Flows***

The following table summarizes our sources and uses of cash for each period presented (in thousands):

| | Three Months Ended March 31, | |
|---|---|---|
| | 2022 | 2021 |
| Net cash (used in) provided by: | | |
| Operating activities | $ (49,295) | $ (41,237) |
| Investing activities | 45,665 | (143,451) |
| Financing activities | 662 | (167) |
| Net decrease in cash, cash equivalents and restricted cash | $ (2,968) | $ (184,855) |

*Operating Activities*

Our cash flows from operating activities are greatly influenced by our use of cash for operating expenses and working capital requirements to support the business. We have historically experienced negative cash flows from operating activities as we invested in developing our platform, drug discovery efforts and related infrastructure.

Net cash used in operating activities increased by approximately $8.1 million from $41.2 million for the three months ended March 31, 2021 to $49.3 million for the three months ended March 31, 2022. The increase was primarily attributable to the increase in net loss incurred in the three months ended March 31, 2022.

*Investing Activities*

For the three months ended March 31, 2022, our net cash provided by investing activities was primarily attributable to proceeds of $194.8 million from the maturity and redemption of marketable securities, offset by purchases of held-to-maturity marketable securities of $148.9 million. For the three months ended March 31, 2021, our net cash used in investing activities was primarily attributable to purchases of held-to-maturity marketable securities of $257.9 million, offset by proceeds of $114.5 million from the maturity and redemption of marketable securities.

*Financing Activities*

For the three months ended March 31, 2022, our net cash provided by financing activities was attributable to proceeds of $0.7 million from the exercise of options to purchase common stock, offset by the payment of $0.1 million of public offering costs. For the three months ended March 31, 2021, our net cash used in financing activities was attributable to proceeds of $0.3 million from the exercise of options to purchase common stock, offset by the payment of $0.5 million of public offering costs.

*Plan of Operation and Funding Requirements*

We expect our expenses to increase substantially in connection with our ongoing research and development activities, particularly as we advance the preclinical and clinical activities of our programs. If we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution, which costs we might offset through entry into collaboration agreements with third parties. In addition, we expect to incur additional costs associated with operating as a public company. As a result, we expect to incur substantial operating losses and negative operating cash flows in the foreseeable future.

As of March 31, 2022, our cash, cash equivalents and marketable securities of $441.3 million will be sufficient to finance our operating expenses and capital expenditure requirements through the third quarter of 2024. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our capital resources sooner than we expect.

Because of the numerous risks and uncertainties associated with product development, and because the extent to which we may receive payments under collaboration arrangements or enter into collaborations with third parties is unknown, we may incorrectly estimate the timing and amounts of operating expenses and capital expenditures. Our future capital requirements will depend on many factors, including, but not limited to:

- the scope, progress, results and costs of preclinical studies and clinical trials for our programs;
- the number and characteristics of programs and technologies that we develop or may in-license;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the costs necessary to obtain regulatory approvals, if any, for products in the United States and other jurisdictions, and the costs of post-marketing studies that could be required by regulatory authorities in jurisdictions where approval is obtained;
- 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 continuation of our existing licensing arrangements and entry into new collaborations and licensing arrangements;
- the costs we incur in maintaining business operations;
- the costs associated with being a public company;
- the revenue, if any, received from commercial sales of any product candidates for which we receive marketing approval;
- the effect of competing technological and market developments;
- the impact of any business interruptions to our operations or to those of our manufacturers, suppliers, or other vendors resulting from the COVID-19 pandemic, a similar public health crisis or political or economic instability, such as global conflicts and inflation;
- the impact of political and economic instability to the costs of labor, raw materials and research and development; and
- the extent to which we acquire or invest in businesses, products and technologies, including entering into licensing or collaboration arrangements for programs.

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time consuming, expensive and uncertain process that takes 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 products that we do not expect to be commercially available for many years, if ever. Accordingly, we will need to obtain substantial additional funds to achieve our business objectives.

Adequate additional funds may not be available to us on acceptable terms, or at all. We do not currently have any committed external source of funds. Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances, and marketing, distribution, or licensing arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Market volatility resulting from the COVID-19 pandemic, higher interest rates, diminished credit availability, or other factors could also adversely impact our ability to access capital as and when needed. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of holders of our common stock. Additional debt financing and preferred equity offerings, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring debt, making capital expenditures or declaring dividends and may require the issuance of warrants, which could potentially result in dilution to the holders of our common stock.

If we raise additional funds through strategic collaborations or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity offerings or debt financings when needed, we may be required to delay, limit or terminate our product development programs or any future commercialization efforts or grant rights to develop and market product candidates to third parties that we would otherwise prefer to develop and market ourselves.

**Critical Accounting Policies and Significant Judgments and Estimates**

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

There have been no material changes to our critical accounting policies from those described under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies and Significant Judgments and Estimates" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021 filed with the SEC on March 1, 2022, with the exception of those noted within Note 2 to our unaudited condensed consolidated financial statements included in Part I, Item 1, "Notes to Condensed Consolidated Financial Statements," of this Quarterly Report on Form 10-Q.

**Recently Issued Accounting Pronouncements**

We have reviewed all recently issued standards and have determined that, other than as disclosed in Note 2 to our unaudited condensed consolidated financial statements included in Part I, Item 1, "Notes to Condensed Consolidated Financial Statements," of this Quarterly Report on Form 10-Q, such standards will not have a material impact on our unaudited condensed consolidated financial statements or do not otherwise apply to our operations.

**Item 3. Quantitative and Qualitative Disclosures About Market Risk.**

***Interest rate fluctuation risk***

We are exposed to market risk related to changes in interest rates. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our cash equivalents and marketable securities are primarily invested in U.S. Treasury securities, U.S. Government agency securities, corporate debt securities, commercial paper, repurchase agreements and money market funds. However, an immediate change in market interest rates of 100 basis points would not have a material impact on the fair market value of our investment portfolio or on our financial position or results of operations.

***Foreign currency fluctuation risk***

We are not currently exposed to significant market risk related to changes in foreign currency exchange rates; however, we have contracted with and may continue to contract with foreign vendors. Our operations may be subject to fluctuations in foreign currency exchange rates in the future. While we have not engaged in the hedging of our foreign currency transactions to date, we are evaluating the costs and benefits of initiating such a program and may in the future hedge selected significant transactions denominated in currencies other than the U.S. dollar as we expand our international operations and our risk grows.

***Inflation fluctuation risk***

Inflation generally affects us by increasing our cost of labor, raw materials and research and development. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the three months ended March 31, 2022 and 2021.

**Item 4. Controls and Procedures.**

***Management's Evaluation of our Disclosure Controls and Procedures***

We maintain "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (ii) accumulated and communicated to our management, including our principal executive and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their control objectives.

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of March 31, 2022, the end of the period covered by this Quarterly Report on Form 10-Q. Based upon such evaluation, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of such date.

***Changes in Internal Control over Financial Reporting***

There was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## PART II—OTHER INFORMATION

### Item 1. Legal Proceedings.

From time to time, we may be involved in lawsuits, claims, investigations and proceedings, consisting of intellectual property, commercial, employment and other matters which arise in the ordinary course of business. While the outcome of any such proceedings cannot be predicted with certainty, as of March 31, 2022, we were not party to any legal proceedings that we would expect to have a material adverse impact on our financial position, results of operations or cash flow.

### Item 1A. Risk Factors.

*In evaluating the Company and our business, careful consideration should be given to the following risk factors, in addition to the other information set forth in this Quarterly Report on Form 10-Q and in other documents that we file with the U.S. Securities and Exchange Commission, or the SEC. Investing in our common stock involves a high degree of risk. If any of the following risks and uncertainties actually occurs, our business, prospects, financial condition or results of operations could be materially and adversely affected. The materials and other risks and uncertainties summarized above and described below are not intended to be exhaustive and are not the only risks facing the Company. New risk factors can emerge from time to time, and it is not possible to predict the impact that any factor or combination of factors may have on our business, prospects, financial condition or results of operations.*

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

Risks Related to Past Financial Condition

***We are a clinical-stage biopharmaceutical company with a limited operating history, and have not generated any revenue to date from drug sales, and may never become profitable.***

Biopharmaceutical drug development is a highly speculative undertaking and involves a substantial degree of risk. We were incorporated in June 2007 as Forma Pharmaceuticals, Inc. Our operations to date have been limited primarily to organizing and staffing our company, business planning, raising capital, researching and developing our drug discovery technology, developing our pipeline, building our intellectual property portfolio, undertaking preclinical and clinical studies of our product candidates and pursuing partnerships for our product candidates. We have never generated any revenue from drug sales. We have not obtained regulatory approvals for any of our current product candidates and may not obtain regulatory approvals for our future product candidates, if any.

Typically, it takes many years to develop one new pharmaceutical drug from the time it is discovered to when it is available for treating patients. Consequently, any predictions we make about our future success or viability may not be as accurate as they could be if we had a longer operating history. In addition, as a new business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors, such as the ongoing coronavirus disease 2019, or COVID-19, global pandemic. We will need to transition from a company with a research and development focus to a company capable of supporting late-stage development and commercial activities. We may not be successful in such a transition.

***We have incurred significant operating losses in recent periods and anticipate that we will incur continued losses for the foreseeable future.***

Since inception, we have focused substantially all of our efforts and financial resources on developing our proprietary compound libraries, novel target discovery engine and initial product candidates as well as supporting our collaborations and partnerships. To date, we have financed our operations primarily with proceeds from our license and collaboration agreements, through the issuance and sale of our preferred shares and preferred stock to outside investors and the completion of our initial public offering, or our IPO, and follow-on public offering. From inception through March 31, 2022, we have raised an aggregate of $144.0 million in gross proceeds from sales of our preferred shares and preferred stock, $551.9 million in net proceeds from the sale of our common stock, and approximately $895.8 million in proceeds from our collaboration arrangements with third parties. In March 2019, we declared and, in March 2019 and April 2019 made, a one-time distribution in the aggregate amount of approximately $44.0 million among various of our then-shareholders as a partial return of investment capital. As of March 31, 2022, we had cash, cash equivalents and marketable securities of $441.3 million. Although we have been profitable in prior years, due to our significant research and development expenditures and the termination of certain collaboration arrangements, we have experienced periods of negative cash flows from operations, even in periods of operating income. For the three months ended March 31, 2022, we experienced a loss from operations and negative cash flows from operations. Substantially all of our operating losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to continue to incur significant expenses and operating losses over the next several years and for the foreseeable future. Our prior losses, combined with expected future losses, have had and will

continue to have an adverse effect on our stockholders' equity and working capital. We expect our expenses to significantly increase in connection with our ongoing activities, as we:

- complete preclinical studies, initiate and complete clinical trials for product candidates;
- continue our registration-enabling, global pivotal Phase II/III clinical trial of etavopivat in SCD patients, which we refer to as the Hibiscus Study;
- proceed with our Phase II clinical trial of etavopivat in patients with either transfusion dependent SCD, transfusion dependent thalassemia, or non-transfusion dependent thalassemia;
- continue enrollment in our Phase I study for FT-7051 for the treatment of metastatic castration-resistant prostate cancer, or mCRPC;
- contract to manufacture our product candidates;
- advance research and development related activities to expand our product pipeline;
- seek regulatory approval for our product candidates that successfully complete clinical development;
- develop and scale up our capabilities to support our ongoing preclinical activities and clinical trials for our drug candidates and commercialization of any of our drug candidates for which we obtain marketing approval;
- maintain, expand, enforce, defend and protect our intellectual property portfolio;
- hire additional staff, including clinical, scientific and management personnel;
- continue to take temporary precautionary measures to help minimize the risk of COVID-19 to our employees and patients who enroll in our studies;
- secure facilities to support continued growth in our research, development, and commercialization efforts; and
- incur costs associated with our continued operation as a public company.

In addition, if we obtain marketing approval for our current or future product candidates, we will incur significant expenses relating to sales, marketing, product manufacturing and distribution. Because of the numerous risks and uncertainties associated with developing pharmaceutical drugs, particularly in the ongoing evolution of the COVID-19 pandemic, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis.

Our ability to become profitable depends upon our ability to generate revenue. To date, while we have generated significant research collaboration revenue, we have not generated any commercial revenue from our current product candidates, including our lead product candidate, etavopivat, and our other product candidate, FT-7051, and we do not know and do not expect to generate any revenue from the sale of drugs in the near future. We do not expect to generate revenue unless and until we complete the development of, obtain marketing approval for, and begin to sell, etavopivat, which is currently being evaluated in a Phase II/III trial and a Phase II trial, or FT-7051, which is also currently being evaluated in a Phase I clinical trial. We are also unable to predict when, if ever, we will be able to generate revenue from such product candidates due to the numerous risks and uncertainties associated with drug development, including the uncertainty of:

- our ability to add and retain key research, pharmaceutical sciences and development personnel;
- our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize, etavopivat and FT-7051;
- our successful enrollment in and completion of clinical trials, including our ability to generate positive data from any such clinical trials;
- the costs associated with the development of any additional development programs we identify in-house or acquire through collaborations or other arrangements;
- our ability to discover, develop and utilize biomarkers to demonstrate target engagement, pathway engagement and the impact on disease progression, as applicable, of our product candidates;
- our ability to establish and maintain agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing;
- our ability to forecast and meet supply requirements for clinical trials and commercialized products using third-party manufacturers;
- the terms and timing of any additional collaboration, license or other arrangement, including the terms and timing of any payments thereunder;
- the ability to develop and obtain clearance or approval of companion diagnostic tests, if required, on a timely basis, or at all;
- obtaining and maintaining third-party coverage and adequate reimbursement, if etavopivat or FT-7051 is approved;

- acceptance of our lead product candidates, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies, if etavopivat or FT-7051 is approved;
- our ability to obtain and maintain patent, trade secret and other intellectual property protection for etavopivat and FT-7051 and regulatory exclusivity for etavopivat and FT-7051 if and when approved;
- our receipt of marketing approvals for etavopivat and FT-7051 from applicable regulatory authorities; and
- the continued acceptable safety profiles of our lead products following approval.

We expect to incur significant sales and marketing costs as we prepare to commercialize our current or future product candidates. Even if we initiate and successfully complete pivotal or registration-enabling clinical trials of our current or future product candidates, and our current or future product candidates are approved for commercial sale, and despite expending these costs, our current or future product candidates may not be commercially successful. We may not achieve profitability soon after generating drug sales, if ever. If we are unable to generate revenue, we will not become profitable and may be unable to continue operations without continued funding.

Risks Related to Future Financial Condition

***We will require additional capital to finance our operations, which may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, scale back or discontinue some of our product candidate development programs or pre-commercialization efforts.***

The development of pharmaceutical drugs is capital intensive. We are currently advancing etavopivat and FT-7051 through clinical development. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, advance the preclinical and clinical activities of, and seek marketing approval for, our current or future product candidates. In addition, depending on the status of regulatory approval or, if we obtain marketing approval for any of our current or future product candidates, we expect to incur significant commercialization expenses related to sales, marketing, product manufacturing and distribution to the extent that such sales, marketing, product manufacturing and distribution are not the responsibility of our collaborators. We may also need to raise additional funds sooner if we choose to pursue additional indications and/or geographies for our current or future product candidates or otherwise expand more rapidly than we presently anticipate. We will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on favorable terms, we would be forced to delay, scale back or discontinue the development and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions.

On June 23, 2020 and December 15, 2020, we completed our IPO and our follow-on public offering of our common stock, respectively, and expect that the net proceeds from our IPO and follow-on financing, together with our existing cash, cash equivalents and marketable securities, will be sufficient to fund our operations through the third quarter of 2024. Our forecast of the period of time through which our financial resources will adequately support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this ‘‘Risk Factors’’ section. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Our future capital requirements will depend on and could increase significantly as a result of many factors, including:

- the scope, progress, results and costs of drug discovery, preclinical development, laboratory testing and clinical trials for our current or future product candidates;
- the potential additional expenses attributable to adjusting our development plans (including any supply related matters) to the ongoing COVID-19 pandemic;
- the scope, prioritization and number of our research and development programs;
- the costs, timing and outcome of regulatory review of our current or future product candidates;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- the achievement of milestones or occurrence of other developments that trigger payments under any additional collaboration agreements we obtain;
- the extent to which we are obligated to reimburse, or entitled to reimbursement of, clinical trial costs under future collaboration agreements, if any;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the extent to which we acquire or in-license other current or future product candidates and technologies;
- the costs of securing manufacturing arrangements for commercial production; and

- the costs of establishing or contracting for sales and marketing capabilities if we obtain regulatory approvals to market our current or future product candidates.

Identifying potential current or future product candidates and conducting preclinical development testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve drug sales. In addition, our current or future product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of drugs that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional funding to achieve our business objectives.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our current or future product candidates. Disruptions in the financial markets in general and more recently due to the COVID-19 pandemic, higher interest rates, diminished credit availability and global political and economic instability, have made equity and debt financing more difficult to obtain, and may have a material adverse effect on our ability to meet our fundraising needs. We cannot guarantee that future financing will be available in sufficient amounts or on terms favorable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute all of our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations, and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborators or otherwise at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or current or future product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects.

If we are unable to obtain funding on a timely basis, we may be required to significantly delay, scale back or discontinue one or more of our research or development programs or the commercialization of any product candidates or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

**Risks Related to Drug Development and Regulatory Approval**

Risks Related to Clinical Development

***We depend heavily on the success of our lead product candidates, etavopivat and FT-7051. We cannot be certain that we will be able to obtain regulatory approval for, or successfully commercialize, any of our current or future product candidates.***

We currently have no product candidates approved for sale and may never be able to develop marketable product candidates. Our business depends heavily on the successful development, regulatory approval and commercialization of the current or future product candidates in our lead program in SCD, of which our lead product candidate, etavopivat, is in a Phase II/III clinical development for SCD and a Phase II clinical development for transfusion dependent SCD, transfusion dependent thalassemia, and non-transfusion dependent thalassemia . Etavopivat will require substantial additional clinical development, testing and regulatory approval before we are permitted to commence its commercialization. Our other product candidate, FT-7051, is in Phase I development for the treatment of mCRPC. The preclinical studies and clinical trials of our current or future product candidates are, and the manufacturing and marketing of our current or future product candidates will be, subject to extensive and rigorous review and regulation by numerous government authorities in the U.S. and in other countries where we intend to test or, if approved, market any of our current or future product candidates. Before obtaining regulatory approvals for the commercial sale of any of our current or future product candidates, we must demonstrate through preclinical studies and clinical trials that each product candidate is safe and effective for use in each target indication. Drug development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical trials. This process can take many years and may include post-marketing studies and surveillance, which will require the expenditure of substantial resources. Of the large number of drugs in development in the U.S., only a small percentage will successfully complete the U.S. Food and Drug Administration, or FDA, regulatory approval process and will be commercialized, with similarly low rates of success for drugs in development in the European Union obtaining regulatory approval from the European Medicines Agency, or EMA. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development and preclinical studies and clinical trials, we cannot assure you that any of our current or future product candidates will be successfully developed or commercialized.

We are not permitted to market our current or future product candidates in the U.S. until we receive approval of a New Drug Application, or an NDA, from the FDA, in the European Economic Area, or EEA, until we receive approval of a marketing authorization applications, or an MAA, from the EMA or in any other foreign countries until we receive the requisite approval from such countries. Obtaining approval of an NDA or MAA is a complex, lengthy, expensive and uncertain process, and the FDA or EMA may delay, limit or deny approval of any of our current or future product candidates for many reasons, including, among others:

- we may not be able to demonstrate that our current or future product candidates are safe and effective in treating their target indications to the satisfaction of the FDA or applicable foreign regulatory agency;
- the results of our preclinical studies and clinical trials may not meet the level of statistical or clinical significance required by the FDA or applicable foreign regulatory agency for marketing approval;
- the FDA or applicable foreign regulatory agency may disagree with the number, design, size, conduct or implementation of our preclinical studies and clinical trials;
- the FDA or applicable foreign regulatory agency may require that we conduct additional preclinical studies and clinical trials;
- the FDA or applicable foreign regulatory agency may not approve the formulation, labeling or specifications of any of our current or future product candidates;
- the contract research organizations, or CROs, that we retain to conduct our preclinical studies and clinical trials may take actions that materially adversely impact our preclinical studies and clinical trials;
- the FDA or applicable foreign regulatory agency may find the data from preclinical studies and clinical trials insufficient to demonstrate that our current or future product candidates' clinical and other benefits outweigh their safety risks;
- the FDA or applicable foreign regulatory agency may disagree with our interpretation of data from our preclinical studies and clinical trials;
- the FDA or applicable foreign regulatory agency may not accept data generated at our preclinical studies and clinical trial sites;
- if our NDA, if and when submitted, is reviewed by an advisory committee, the FDA may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;
- the FDA may require development of a Risk Evaluation and Mitigation Strategy, or REMS, as a condition of approval or post-approval;
- the FDA or the applicable foreign regulatory agency may determine that the manufacturing processes or facilities of third-party manufacturers with which we contract do not conform to applicable requirements, including current Good Manufacturing Practices, or cGMPs;
- the FDA or applicable foreign regulatory agency may be delayed in their review processes due to staffing or other constraints arising from the ongoing COVID-19 pandemic; or
- the FDA or applicable foreign regulatory agency may change its approval policies or adopt new regulations.

Any of these factors, many of which are beyond our control, could jeopardize our ability to obtain regulatory approval for and successfully market our current or future product candidates. Any such setback in our pursuit of regulatory approval would have a material adverse effect on our business and prospects.

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

We may not be able to initiate or continue clinical trials for our current or future product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the U.S. In particular, because we are focused on patients with rare hematologic diseases and cancers, our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate. In addition, our ability to enroll patients has been impacted by the evolving COVID-19 pandemic and may be significantly delayed. We do not know the extent and scope of such delays at this point. Moreover, some of our competitors have ongoing clinical trials for current or future product candidates in the same patient populations as our current or future product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' current or future product candidates.

Patient enrollment may be affected by other factors including:

- the willingness of participants to enroll in our clinical trials and available support in our countries of interest;
- the severity of the disease under investigation;
- the eligibility criteria for the clinical trial in question;
- the availability of an appropriate screening test;
- the perceived risks and benefits of the product candidate under study;
- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- the proximity and availability of clinical trial sites for prospective patients; and
- factors we may not be able to control, such as current or potential pandemics that may limit patients, CROs, principal investigators or staff, or clinical site availability (*e.g.*, outbreak of COVID-19, including as a result of new variants of the virus).

***Rare hematologic diseases may have relatively low prevalence and it may be difficult to identify patients with the driver of the disease, which may lead to delays in enrollment for our trials.***

Rare hematologic diseases may have relatively low prevalence and it may be difficult to identify patients with the indications we are targeting. For example, the prevalence of SCD is approximately 100,000 individuals in the U.S. and approximately 30,000 individuals in France, Germany, Italy, Spain and the United Kingdom on a combined basis. Similarly, the prevalence of beta thalassemia is estimated to be approximately 20,000 individuals across the U.S. and Europe and approximately 300,000 patients globally. Our inability to enroll a sufficient number of patients with the target indication for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our current or future product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing. We have currently received Fast Track, Rare Pediatric Disease and Orphan Drug designations from the FDA for etavopivat in SCD patients. The European Commission also granted Orphan Drug designation to etavopivat for the treatment of SCD. However, if we are unable to include patients with the target indication, this could compromise our ability to seek participation in the FDA's expedited review and approval programs, including Breakthrough Therapy Designation and Fast Track Designation, or otherwise to seek to accelerate clinical development and regulatory timelines for our other product candidates.

***Business interruptions resulting from the COVID-19 pandemic or similar public health crises could cause a disruption to the development of our product candidates and adversely impact our business.***

Public health crises such as pandemics or similar outbreaks could adversely impact our business. In December 2019, a novel strain of a virus named SARS-CoV-2, which causes COVID-19 surfaced in Wuhan, China and has reached multiple other regions and countries, including Watertown, Massachusetts where our primary office and laboratory space is located. The ongoing global COVID-19 pandemic is evolving, and to date has led to the implementation of various responses, including government-imposed quarantines, travel restrictions, vaccination mandates and other public health safety measures. The extent to which the COVID-19 pandemic impacts our operations or those of our third-party partners, including our preclinical studies or clinical trial operations, will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak, new information concerning the severity of the COVID-19 pandemic, the impact of new strains of COVID-19, such as Delta and Omicron, the effectiveness, availability and utilization of vaccines and boosters, the actions to contain the coronavirus or treat its impact, among others. The continued spread of COVID-19 globally could adversely impact our preclinical or clinical trial operations in the U.S. (and outside of the U.S.), including our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if an outbreak occurs in their geography. A rise in the number of COVID-19 cases, including as a result of new variants of the virus, could cause a more widespread or severe impact on commercial activity depending on where infection rates are highest. For example, similar to other biopharmaceutical companies, our ability to enroll patients in clinical trials has been impacted and we are experiencing delays in the dosing of patients in our clinical trials as well as in activating new trial sites. The COVID-19 pandemic may also affect employees of third-party CROs or contract manufacturing organizations, or CMOs, located in affected geographies that we rely upon to carry out our clinical trials. For example, since the beginning of the COVID-19 pandemic, three vaccines for COVID-19 have received Emergency Use Authorization by the FDA and two of those later received marketing approval. Additional vaccines may be authorized or approved in the future. The resultant demand for vaccines and potential for manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, may make it more difficult to obtain materials or manufacturing slots for the products needed for our clinical trials, which could lead to delays in these trials. In addition, as a result of medical complications associated with SCD and mCRPC, the patient populations that our lead and other product candidates target may be particularly susceptible to COVID-19, which may make it more difficult for us to identify patients able to enroll in our current and future clinical trials and may impact the ability of enrolled patients to complete any such trials. Any negative impact COVID-19 has to patient enrollment or treatment or the execution of our product candidates could cause costly delays to clinical trial activities, which could adversely affect our ability to obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses, and have a material adverse effect on our financial results.

Additionally, timely enrollment in planned clinical trials is dependent upon clinical trial sites which will be adversely affected by global health matters, such as pandemics. We plan to conduct clinical trials for our product candidates in geographies which are currently being affected by the COVID-19 pandemic. Some factors from the coronavirus outbreak that will delay or otherwise adversely affect enrollment in the clinical trials of our product candidates, as well as our business generally, include:

- the potential diversion of healthcare resources away from the conduct of clinical trials to focus on pandemic concerns, including the attention of physicians serving as our clinical trial investigators, hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our prospective clinical trials;
- limitations on travel that could interrupt key trial and business activities, such as clinical trial site initiations and monitoring, domestic and international travel by employees, contractors or patients to clinical trial sites, including any government-imposed travel restrictions or quarantines that will impact the ability or willingness of patients, employees or contractors to travel to our clinical trial sites or secure visas or entry permissions, a loss of face-to-face meetings and other interactions with potential partners, any of which could delay or adversely impact the conduct or progress of our prospective clinical trials;
- the potential negative effect on the operations of our third-party manufacturers;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA and other comparable foreign regulatory authorities;
- interruption in global shipping affecting the transport of clinical trial materials, such as patient samples, investigational drug product and conditioning drugs and other supplies used in our prospective clinical trials; and
- business disruptions caused by potential workplace, laboratory and office closures and an increased reliance on employees working from home, disruptions to or delays in ongoing laboratory experiments and operations, staffing shortages, travel limitations or mass transit disruptions, any of which could adversely impact our business operations or delay necessary interactions with local regulators, ethics committees and other important agencies and contractors.

We have taken temporary precautionary measures intended to help minimize the risk of the virus to our employees, including temporarily requiring employees to work remotely, suspending all non-essential travel worldwide for our employees and employee attendance at industry events and in-person work-related meetings, which could negatively affect our business. In accordance with applicable state requirements, laboratory employees returned to our laboratories on May 19, 2020 on a voluntary basis and the Company is keeping the safety of these workers as a top priority. We cannot presently predict the scope and severity of the planned and potential shutdowns or disruptions of businesses and government agencies, such as the SEC, the FDA or its foreign equivalent.

These and other factors arising from the coronavirus could worsen in countries that are already afflicted with the coronavirus or could continue to spread to additional countries. Any of these factors, and other factors related to any such disruptions that are unforeseen, could have a material adverse effect on our business and our results of operations and financial condition. Further, uncertainty around these and related issues could lead to adverse effects on the economy of the United States and other economies, which could impact our ability to raise the necessary capital needed to develop and commercialize our product candidates.

***Our current or future product candidates may cause adverse or other undesirable side effects that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.***

Undesirable side effects caused by our current or future product candidates could cause us to interrupt, delay or halt preclinical studies or could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other regulatory authorities. While we have initiated clinical trials for etavopivat and FT-7051, it is likely that there may be adverse side effects associated with their use. Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, our trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our current or future product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Further, our current or future product candidates could cause undesirable side effects in clinical trials related to on-target toxicity. If on-target toxicity is observed, or if our current or future product candidates have characteristics that are unexpected, we may need to 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. Many compounds that initially showed promise in early-stage testing for treating cancer have later been found to cause side effects that prevented further development of the compound.

Further, clinical trials by their nature utilize a sample of the potential patient population. For example, the single dose cohort in our Phase I trial of etavopivat only included seven SCD patients. With a limited number of patients and limited duration of exposure, rare and severe side effects of our current or future product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidate. If our current or future product candidates receive marketing approval and we or others identify undesirable side effects caused by such current or future product candidates (or any other similar drugs) after such approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of such current or future product candidates;
- regulatory authorities may require the addition of labeling statements, such as a “boxed” warning or a contraindication;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way such current or future product candidates are distributed or administered, conduct additional clinical trials or change the labeling of the current or future product candidates;
- regulatory authorities may require a REMS plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools;
- we may be subject to regulatory investigations and government enforcement actions;
- we may decide to remove such current or future product candidates from the marketplace;

- we could be sued and held liable for injury caused to individuals exposed to or taking our current or future product candidates; and
- our reputation may suffer.

We believe that any of these events could prevent us from achieving or maintaining market acceptance of the affected current or future product candidates and could substantially increase the costs of commercializing our current or future product candidates, if approved, and significantly impact our ability to successfully commercialize our current or future product candidates and generate revenues.

***Positive results from early preclinical studies and clinical trials of our current or future product candidates are not necessarily predictive of the results of later preclinical studies and clinical trials of our current or future product candidates. If we cannot replicate the positive results from our earlier preclinical studies and clinical trials of our current or future product candidates in our later preclinical studies and clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize our current or future product candidates.***

From time to time, we may disclose or publish partial, interim, top-line or preliminary results from our preclinical studies or clinical trials. Such clinical results 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. Partial and interim results are subject to the completion of a given clinical trial cohort and the balance of the data for such cohort. Partial, interim, preliminary or top-line results also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. Accordingly, positive results from our preclinical studies of our current or future product candidates, and any positive top-line, partial, interim or other preliminary results we may obtain from our clinical trials of our current or future product candidates, may not necessarily be predictive of the results from required later preclinical studies and clinical trials. Similarly, even if we are able to complete our planned preclinical studies or clinical trials of our current or future product candidates according to our current development timeline, the positive results from our preclinical studies and clinical trials of our current or future product candidates may not be replicated in subsequent preclinical studies or clinical trial results. For example, our later-stage clinical trials could differ in significant ways from our Phase I clinical trial of etavopivat and our ongoing Phase I clinical trial of FT-7051, which could cause the outcome of these later-stage trials to differ from our earlier stage clinical trials. For example, these differences may include changes to inclusion and exclusion criteria, final dosage formulation, efficacy endpoints and statistical design. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events, or AEs. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA approval. If we fail to produce positive results in our planned preclinical studies or clinical trials of any of our current or future product candidates, or such later studies or trials otherwise generated data or results that differ significantly from data or results seen in prior studies or trials, the development timeline and regulatory approval and commercialization prospects for our current or future product candidates, and, correspondingly, our business and financial prospects, would be materially adversely affected.

Additionally, several of our past, planned and ongoing clinical trials utilize an “open-label” trial design. An “open-label” clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a “patient bias” where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an “investigator bias” where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open-label trial may not be predictive of future clinical trial results with any of our product candidates for which we include an open-label clinical trial when studied in a controlled environment with a placebo or active control.

***Even if we receive marketing approval for our current or future product candidates in the U.S., we may never receive regulatory approval to market our current or future product candidates outside of the U.S.***

We plan to seek regulatory approval of our current or future product candidates outside of the U.S. In order to market any product outside of the U.S., however, we must establish and comply with the numerous and varying safety, efficacy and

other regulatory requirements of other countries. Approval procedures vary among countries and can involve additional product candidate testing and additional administrative review periods. The time required to obtain approvals in other countries might differ from that required to obtain FDA approval. The marketing approval processes in other countries may implicate all of the risks detailed above regarding FDA approval in the U.S. as well as other risks. In particular, in many countries outside of the U.S., products must receive pricing and reimbursement approval before the product can be commercialized. Obtaining this approval can result in substantial delays in bringing products to market in such countries. Marketing approval in one country does not ensure marketing approval in another, but a failure or delay in obtaining marketing approval in one country may have a negative effect on the regulatory process in others. Failure to obtain marketing approval in other countries or any delay or other setback in obtaining such approval would impair our ability to market our current or future product candidates in such foreign markets. Any such impairment would reduce the size of our potential market, which could have a material adverse impact on our business, results of operations and prospects.

Risks Related to Regulatory Approval

***If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals both for our current or future product candidates, we will not be able to commercialize, or will be delayed in commercializing, our current or future product candidates, and our ability to generate revenue will be materially impaired.***

Our current or future product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export are subject to comprehensive regulation by the FDA and other regulatory agencies in the U.S. and by comparable authorities in other countries. Before we can commercialize any of our current or future product candidates, we must obtain marketing approval. We have not received approval to market any of our current product candidates and may not obtain regulatory approvals for our future product candidates, if any, from regulatory authorities in any jurisdiction and it is possible that none of our current or future product candidates or any current or future product candidates we may seek to develop in the future will ever obtain regulatory approval. We have only limited experience in filing and supporting the applications necessary to gain regulatory approvals and expect to rely on third-party CROs and/or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication and line of treatment to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Our current or future product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining regulatory approvals, both in the U.S. and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the current or future product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted NDA, premarket approval application, or PMA, application for a companion diagnostic test or equivalent application types, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, government agencies beyond the FDA and comparable authorities may exert political influence regarding prior or future regulatory approvals and related processes, resulting in changes in policies and guidance by the regulatory authorities in question. Our current or future product candidates could be delayed in receiving, as a result of required changes in our timelines or regulatory strategy, or fail to receive, regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication or that it is suitable to identify appropriate patient populations;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;

- the data collected from clinical trials of our current or future product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the U.S. or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Additionally, as of May 26, 2021, the FDA noted it is continuing to ensure timely reviews of applications for medical products during the ongoing COVID-19 pandemic in line with its user fee performance goals. However, the FDA may not be able to continue its current pace and review timelines could be extended including where a pre-approval inspection or an inspection of clinical sites is required and due to the ongoing COVID-19 pandemic and travel restrictions the FDA is unable to complete such required inspections during the review period. During the COVID-19 public health emergency, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications.

Even if we were to obtain approval, regulatory authorities may approve any of our current or future product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our drugs, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our current or future product candidates.

If we experience delays in obtaining approval or if we fail to obtain approval of our current or future product candidates, the commercial prospects for our current or future product candidates may be harmed and our ability to generate revenues will be materially impaired.

***A Breakthrough Therapy Designation by the FDA for our current or future product candidates may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our current or future product candidates will receive marketing approval.***

We may seek a Breakthrough Therapy Designation for some of our current or future product candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA may also be eligible for accelerated approval.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe that one of our current or future product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy Designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our current or future product candidates qualify as breakthrough therapies, the FDA may later decide that the drugs no longer meet the conditions for qualification.

***If we are delayed or not able to establish eligibility for accelerated approval by the FDA, or it determines accelerated approval is not warranted, for etavopivat the timeline and costs of our development program may be materially increased, and even if granted for any of our product candidates, accelerated approval may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive regulatory approval.***

We have been pursuing accelerated approval for etavopivat and may seek accelerated approval of our other current or future product candidates using the FDA's accelerated approval pathway. A product may be eligible for accelerated approval if it treats a serious or life-threatening condition and provides a meaningful therapeutic benefit to patients over existing treatments. In addition, it must demonstrate an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. It is possible that the FDA may determine that our product candidate is not eligible for accelerated approval or that accelerated approval is not warranted. Moreover, FDA may revise how it implements accelerated approval. Based on ongoing feedback from the FDA, although accelerated approval is still an available regulatory pathway for etavopivat for the treatment of SCD, we will need to provide additional information to support hemoglobin

response as a surrogate endpoint eligible for accelerated approval for etavopivat. We plan to continue to seek accelerated approval for etavopivat utilizing hemoglobin response rates as a surrogate endpoint by providing additional data to support that hemoglobin response rates predict for a clinical benefit. If we are delayed or not successful in establishing eligibility for accelerated approval with the FDA, or if the FDA determines accelerated approval is not warranted, our development timelines and costs associated with etavopivat may be materially increased.

As a condition of approval, the FDA requires that a sponsor of a drug receiving accelerated approval perform post-marketing clinical trial(s) to confirm clinical benefit. Any confirmatory trial must be completed with due diligence. In addition, the FDA requires, unless otherwise informed by the agency, pre-approval of promotional materials for products receiving accelerated approval, which could adversely impact the timing of the commercial launch of the product. Even if we do reach agreement with the FDA that etavopivat is eligible for accelerated approval, we may not experience a faster development or regulatory review or approval process. In addition, receiving accelerated approval does not assure that the product's accelerated approval will eventually be converted to a traditional approval.

***A Fast Track Designation by the FDA may not actually lead to a faster development or regulatory review or approval process.***

We have received Fast Track Designation from the FDA for etavopivat in SCD patients. We may seek Fast Track Designation for our other current or future product candidates. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for Fast Track Designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe that a particular product candidate is eligible for this designation, we cannot assure that the FDA would decide to grant it. Even though we have received Fast Track Designation and may receive Fast Track Designation again in the future for certain current or future product candidates, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program.

***We may not be able to obtain or maintain Orphan Drug Designation or exclusivity for any product candidates and, even if we do, that exclusivity may not prevent the FDA or the EMA from approving other competing products.***

We have received Orphan Drug designation from the FDA for etavopivat in SCD patients. The European Commission also granted Orphan Drug designation to etavopivat for the treatment of SCD. We may seek Orphan Drug Designation for other current or future product candidates. Regulatory authorities in some jurisdictions, including the U.S. and the European Union, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the U.S.

Generally, if a product with an Orphan Drug Designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the EMA from approving another marketing application for the same drug for that time period. The applicable period is seven years in the U.S. and ten years in the European Union. The exclusivity period in the European Union can be reduced to six years if a drug no longer meets the criteria for Orphan Drug Designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan Drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

Even if we obtain Orphan Drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because competing drugs containing a different active ingredient can be approved for the same condition. In addition, even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. Further, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products, and thus, for example, approval of our product candidates could be blocked for seven years if another company previously obtained approval and orphan drug exclusivity in the United States for the same drug and same condition.

The FDA may further reevaluate the Orphan Drug Act and its regulations and policies. We do not know if, when or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its Orphan Drug regulations and policies, our business could be adversely impacted.

***Although we have obtained Rare Pediatric Disease Designation from the FDA for etavopivat in SCD patients, we may not be eligible to receive a priority review voucher in the event that FDA approval does not occur prior to September 30, 2026.***

The Rare Pediatric Disease Priority Review Voucher Program, or PRV Program, is intended to incentivize pharmaceutical sponsors to develop drugs for rare pediatric diseases. A sponsor who obtains approval of an NDA for a rare pediatric disease may be eligible for a Priority Review Voucher, or PRV, under this program, which may be redeemed by the owner of such PRV to obtain priority review for a marketing application. A PRV is fully transferrable and can be sold to any sponsor, who in turn can redeem the PRV for priority review of a marketing application in six months, compared to the standard timeframe of approximately 10 months. The authority for the FDA to award PRVs for drugs after September 30, 2024 is currently limited to drugs that receive rare pediatric disease designation on or prior to September 30, 2024, and the FDA may only award PRVs through September 30, 2026. However, it is possible the authority for the FDA to award PRVs will be extended by Congress. As such, although we have obtained Rare Pediatric Disease Designation from the FDA for etavopivat in SCD patients, if we do not obtain approval of an NDA for etavopivat in patients with SCD on or before September 30, 2026, and if the PRV Program is not extended by Congressional action, we may not receive a PRV.

***Even if we receive regulatory approval for any of our current or future product candidates, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our current or future product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our drugs.***

If the FDA or a comparable foreign regulatory authority approves any of our current or future product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the drug will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, compliance with applicable product tracking and tracing requirements, as well as continued compliance with cGMPs and Good Clinical Practices, or GCPs, for any clinical trials that we conduct post-approval. Any regulatory approvals that we receive for our current or future product candidates may also be subject to limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase IV clinical trials, and surveillance to monitor the safety and efficacy of the drug. Later discovery of previously unknown problems with a drug, including AEs of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the drug, withdrawal of the drug from the market, or voluntary drug recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of drug license approvals;
- drug seizure or detention, or refusal to permit the import or export of drugs; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our current or future 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, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

***Manufacturing our current or future product candidates is complex and we may encounter difficulties in production. If we encounter such difficulties, our ability to provide supply of our current or future product candidates for preclinical studies and clinical trials or for commercial purposes could be delayed or stopped.***

The process of manufacturing of our current or future product candidates is complex and highly regulated. We do not have our own manufacturing facilities or personnel and currently rely, and expect to continue to rely, on third parties based in the U.S., Europe and Asia for the manufacture of our current or future product candidates. These third-party manufacturing providers may not be able to provide adequate resources or capacity to meet our needs and may incorporate their own proprietary processes into our product candidate manufacturing processes. We have limited control and oversight of a third-party's proprietary process, and a third-party may elect to modify its process without our consent or knowledge. These modifications could negatively impact our manufacturing, including product loss or failure that requires additional manufacturing runs or a change in manufacturer, both of which could significantly increase the cost of and significantly delay the manufacture of our current or future product candidates.

As our current or future product candidates progress through preclinical studies and clinical trials towards approval and commercialization, it is expected that various aspects of the manufacturing process will be altered in an effort to optimize processes and results. Such changes may require amendments to be made to regulatory applications which may further delay the timeframes under which modified manufacturing processes can be used for any of our current or future product candidates and additional bridging studies or trials may be required.

***Our future growth may depend, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties that could materially adversely affect our business.***

We are not permitted to market or promote any of our current or future product candidates in foreign markets before we receive regulatory approval from the applicable regulatory authority in that foreign market, and we may never receive such regulatory approval for any of our current or future product candidates. To obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our current or future product candidates, and we cannot predict success in these jurisdictions. If we obtain approval of our current or future product candidates and ultimately commercialize our current or future product candidates in foreign markets, we would be subject to additional risks and uncertainties, including:

- differing regulatory requirements in foreign countries, which may cause obtaining regulatory approvals outside of the U.S. to take longer and be more costly than obtaining approval in the U.S.;
- our customers' ability to obtain reimbursement for our current or future product candidates in foreign markets;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;
- longer accounts receivable collection times;
- longer lead times for shipping;
- language barriers for technical training;
- reduced protection of intellectual property rights in some foreign countries;
- the existence of additional potentially relevant third-party intellectual property rights;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations;
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

Foreign sales of our current or future product candidates could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs.

***We are and may in the future conduct clinical trials for current or future product candidates outside the U.S., and the FDA and comparable foreign regulatory authorities may not accept data from such trials.***

We are and may in the future choose to conduct one or more clinical trials outside the U.S., including in Europe. The acceptance of study data from clinical trials conducted outside the U.S. or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the U.S., the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice and (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable doctrines or local laws of the foreign jurisdictions where the trials are

conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the U.S. or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in current or future product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

***We may not be successful in our efforts to identify or discover additional product candidates or 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.***

The success of our business depends primarily upon our ability to identify, develop and commercialize our product candidates. Although some of our current product candidates are in preclinical and clinical development, our scientific hypotheses may be incorrect or our research programs may fail to identify other potential product candidates for clinical development for a number of reasons. Our research methodologies may be unsuccessful in identifying potential product candidates, or our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval.

Because we have limited financial and management resources, we focus on a limited number of research programs and product candidates and are currently focused on our programs, including our lead product candidate, etavopivat, for the treatment of SCD and of transfusion dependent SCD, transfusion dependent thalassemia, and non-transfusion dependent thalassemia and our other product candidate, FT-7051, for the treatment of mCRPC. As a result, we may forego or delay pursuit of opportunities with other current or future product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. Our spending on current and future research and development programs and current or future product candidates for specific indications may not yield any commercially viable drugs. 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 future 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 to such product candidate.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, which would have a material adverse effect on our business and could potentially cause us to cease operations. Research programs to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or current or future product candidates that ultimately prove to be unsuccessful.

***In light of the large population of patients with SCD who reside in foreign countries, our ability to generate meaningful revenues in those jurisdictions may be limited due to the strict price controls and reimbursement limitations imposed by governments outside of the U.S.***

The prevalence of SCD is approximately 100,000 individuals in the U.S. and approximately 30,000 individuals in France, Germany, Italy, Spain and the United Kingdom collectively. Similarly, the prevalence of beta thalassemia is estimated to be approximately 20,000 individuals across the U.S. and Europe and approximately 300,000 patients globally. In some countries, particularly in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug. To obtain coverage and reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. In addition, many countries outside the U.S. have limited government support programs that provide for reimbursement of drugs such as are product candidates, with an emphasis on private payors for access to commercial products. If reimbursement of our product candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially, based, in part, on the large population of patients with SCD who reside in foreign countries. In parts of Africa and certain countries in the Middle East, the lack of health care infrastructure to help adequately diagnose and treat patients may limit our business potential in those otherwise viable markets.

**Risks Related to Commercialization**

Risks Related to Sales, Marketing and Competition

***Even if we receive marketing approval for our current or future product candidates, our current or future product candidates may not achieve broad market acceptance, which would limit the revenue that we generate from their sales.***

The commercial success of our current or future product candidates, if approved by the FDA or other applicable regulatory authorities, will depend upon the awareness and acceptance of our current or future product candidates among the medical community, including physicians, patients and healthcare payors. Market acceptance of our current or future product candidates, if approved, will depend on a number of factors, including, among others:

- the efficacy of our current or future product candidates as demonstrated in clinical trials, and, if required by any applicable regulatory authority in connection with the approval for the applicable indications, to provide patients with incremental health benefits, as compared with other available medicines;
- limitations or warnings contained in the labeling approved for our current or future product candidates by the FDA or other applicable regulatory authorities;
- the clinical indications for which our current or future product candidates are approved;
- availability of alternative treatments already approved or expected to be commercially launched in the near future;
- the potential and perceived advantages of our current or future product candidates over current treatment options or alternative treatments, including future alternative treatments;
- the willingness of the target patient population to try new therapies or treatment methods and of physicians to prescribe these therapies or methods;
- the need to dose such product candidates in combination with other therapeutic agents, and related costs;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments;
- pricing and cost effectiveness;
- the effectiveness of our sales and marketing strategies;
- our ability to increase awareness of our current or future product candidates;
- our ability to obtain sufficient third-party coverage or reimbursement; or
- the ability or willingness of patients to pay out-of-pocket in the absence of third-party coverage.

If our current or future product candidates are approved but do not achieve an adequate level of acceptance by patients, physicians and payors, we may not generate sufficient revenue from our current or future product candidates to become or remain profitable. Before granting reimbursement approval, healthcare payors may require us to demonstrate that our current or future product candidates, in addition to treating these target indications, also provide incremental health benefits to patients. Our efforts to educate the medical community, patient organizations and third-party payors about the benefits of our current or future product candidates may require significant resources and may never be successful.

***We face substantial competition, which may result in others discovering, developing or commercializing drugs before or more successfully than we do.***

The development and commercialization of new drugs is highly competitive. We face competition with respect to our current product candidates and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell drugs or are pursuing the development of therapies for rare hematologic diseases and cancers, including SCD and mCRPC. Some of these competitive drugs and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Specifically, there are a large number of companies developing or marketing treatments for rare hematologic diseases and cancers, including many major pharmaceutical and biotechnology companies. If etavopivat receives marketing approval for the treatment of SCD, it may face competition from other product candidates in development for these indications, including product candidates in development from bluebird bio, Inc., EpiDestiny, Inc., Novo Nordisk A/S, Sangamo Therapeutics Inc., Bioverativ Inc. (now Sanofi S.A.), Fulcrum Therapeutics, Inc., Editas Medicine Inc., Graphite Bio, Inc., Global Blood Therapeutics, Inc., Merck & Co., Inc., Bristol-Myers Squibb Company, Novartis AG, Agios

Pharmaceuticals, Inc., or Agios, Imara Inc., Aruvant Sciences, Inc., Vertex Pharmaceuticals Incorporated, or CRISPR Therapeutics AG. Further, if FT-7051 receives marketing approval for the treatment of mCRPC, it may face competition from CellCentric, Ltd., Genentech, Inc. and Constellation Pharmaceuticals, Inc.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and reimbursement and marketing approved drugs than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific, sales, marketing and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any drugs that we or our collaborators may develop. Our competitors also may obtain FDA or other regulatory approval for their drugs more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we or our collaborators are able to enter the market. The key competitive factors affecting the success of all of our current or future product candidates, if approved, are likely to be their efficacy, safety, convenience, price, the level of generic competition and the availability of reimbursement from government and other third-party payors.

***Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any current or future product candidates that we may develop.***

We will face an inherent risk of product liability exposure related to the testing of our current or future product candidates in human clinical trials and will face an even greater risk if we commercially sell any current or future product candidates that we may develop. If we cannot successfully defend ourselves against claims that our current or future product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any current or future product candidates that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs and resources to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- the inability to commercialize any current or future product candidates that we may develop.

Although we maintain product liability insurance coverage, it may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage when we initiate a large global trial and if we successfully commercialize any product candidate. Insurance coverage is increasingly expensive. We may not be able to maintain product liability insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

***Even if we are able to commercialize any current or future product candidates, such drugs may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which would harm our business.***

The regulations that govern regulatory approvals, pricing and reimbursement for new drugs vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product candidate in a particular country, but then be subject to price regulations that delay our commercial launch of the product candidate, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product candidate in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more current or future product candidates, even if our current or future product candidates obtain marketing approval.

Our ability to commercialize any current or future product candidates successfully also will depend in part on the extent to which coverage and reimbursement for these current or future product candidates and related treatments will be available

from government authorities, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. For further discussion third-party coverage and reimbursement, see the section of our Annual Report on Form 10-K entitled “Business—Government Regulation—Third-Party Payor Coverage and Reimbursement.”

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting insurance coverage and the amount of reimbursement for particular drugs. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for drugs. We cannot be sure that coverage will be available for any product candidate that we commercialize and, if coverage is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or similar regulatory authorities outside of the U.S. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the U.S. In the U.S., the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, or HHS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved drugs that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize drugs and our overall financial condition.

***Healthcare reform measures may have a material adverse effect on our business and results of operations.***

The U.S. and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our current or future product candidates or any future product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell a product for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements, (ii) additions or modifications to product labeling, (iii) the recall or discontinuation of our products or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business. For further discussion on the impact of healthcare reform on the company, see the section of our Annual Report on Form 10-K entitled “Business—Government Regulation—Healthcare Reform.”

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our current or future product candidates or additional pricing pressures. In particular any policy changes through CMS, as well as local state Medicaid programs, could have a significant impact on our business in light of the higher proportion of SCD patients that utilize Medicare and Medicaid programs to pay for treatments.

Our revenue prospects could be affected by changes in healthcare spending and policy in the U.S. and abroad. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition. We cannot predict the likelihood,

nature or extent of government regulation that may arise from future legislation or administrative action in the United States or any other jurisdiction. It is highly possible that additional governmental action will be taken at either or both the federal and state levels to address the COVID-19 pandemic. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future, including repeal, replacement or significant revisions to the ACA. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our current or future product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain coverage and reimbursement approval for a product;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

***If, in the future, we are unable to establish sales and marketing and patient support capabilities or enter into agreements with third parties to sell and market our current or future product candidates, we may not be successful in commercializing our current or future product candidates if and when they are approved, and we may not be able to generate any revenue.***

We do not currently have a sales or marketing infrastructure and have limited experience in the sales, marketing, patient support or distribution of drugs. To achieve commercial success for any approved product candidate for which we retain sales and marketing responsibilities, we must build our sales, marketing, patient support, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. In the future, we may choose to build a focused sales and marketing infrastructure to sell, or participate in sales activities with our collaborators for, some of our current or future product candidates if and when they are approved.

There are risks involved with both establishing our own sales and marketing and patient support capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any drug launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our current or future product candidates on our own include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future drugs;
- the lack of complementary drugs to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we enter into arrangements with third parties to perform sales, marketing, patient support and distribution services, our drug revenues or the profitability of these drug revenues to us are likely to be lower than if we were to market and sell any current or future product candidates that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our current or future product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our current or future product candidates effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our current or future product candidates. Further, our business, results of operations, financial condition and prospects will be materially adversely affected.

***Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits and future earnings.***

Although we do not currently have any drugs on the market, if we begin commercializing our current or future product candidates, we will be subject to additional healthcare statutory and regulatory requirements and enforcement by the federal government and the states and foreign governments in which we conduct our business. Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of any current or future product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our current or future product candidates for which we obtain marketing approval. See the section of our Annual Report on Form 10-K entitled "Business—Government Regulation—Other Healthcare Laws and Regulations."

Ensuring that our future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations, including anticipated activities to be conducted by our sales team, were to be found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

***We may face potential liability if we obtain identifiable patient health information from clinical trials sponsored by us.***

Most healthcare providers, including certain research institutions from which we may obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA, as amended by the HITECH. We are not currently classified as a covered entity or business associate under HIPAA and thus are not directly subject to its requirements or penalties. However, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information. In addition, in the future, we may maintain sensitive personally identifiable information, including health information, that we receive throughout the clinical trial process, in the course of our research collaborations, and directly from individuals (or their healthcare providers) who may enroll in patient assistance programs if we choose to implement such programs. As such, we may be subject to state laws requiring notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA.

The EU General Data Protection Regulation, or GDPR, also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR includes restrictions on cross-border data transfers. The GDPR may increase our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. Compliance with the GDPR is a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities.

In addition, further to the UK's exit from the EU on January 31, 2020, the GDPR ceased to apply in the UK at the end of the transition period on December 31, 2020. However, as of January 1, 2021, the UK's European Union (Withdrawal) Act 2018 incorporated the GDPR (as it existed on December 31, 2020 but subject to certain UK specific amendments) into UK law, referred to as the UK GDPR. The UK GDPR and the UK Data Protection Act 2018 set out the UK's data protection regime, which is independent from but aligned to the EU's data protection regime. Non-compliance with the UK GDPR may result in monetary penalties of up to £17.5 million or 4% of worldwide revenue, whichever is higher. Although the UK is regarded as a third country under the EU's GDPR, the European Commission, or EC, has now issued a decision recognizing the UK as providing adequate protection under the EU GDPR and, therefore, transfers of personal data originating in the EU to the UK remain unrestricted. Like the EU GDPR, the UK GDPR restricts personal data transfers outside the UK to countries not regarded by the UK as providing adequate protection. The UK government has confirmed that personal data transfers from the UK to the EEA remain free flowing.

In addition, many jurisdictions outside of Europe are also considering and/or enacting comprehensive data protection legislation. For example, as of August 2020, the Brazilian General Data Protection Law imposes stringent requirements similar to GDPR with respect to personal information collected from individuals in Brazil.

In China, there have also been recent significant developments concerning privacy and data security. On June 10, 2021, the Standing Committee of the National People's Congress of the PRC published the Data Security Law of the People's Republic of China, or the Data Security Law, which took effect on September 1, 2021. The Data Security Law requires data processing (which includes the collection, storage, use, processing, transmission, provision and publication of data), to be conducted in a legitimate and proper manner. The Data Security Law imposes data security and privacy obligations on entities and individuals carrying out data processing activities and also introduces a data classification and hierarchical protection system based on the importance of data in economic and social development and the degree of harm it may cause to national security, public interests or legitimate rights and interests of individuals or organizations if such data are tampered with, destroyed, leaked, illegally acquired or illegally used. The appropriate level of protection measures is required to be taken for each respective category of data.

Also in China, on August 20, 2021, the Standing Committee of the National People's Congress of the PRC promulgated the Personal Information Protection Law, which took effect on November 1, 2021. The Personal Information Protection Law raises the protection requirements for processing personal information, and many specific requirements of the Personal Information Protection Law remain to be clarified. We may be required to make further significant adjustments to our business practices to comply with the personal information protection laws and regulations in China including the Personal Information Protection Law.

In addition, California recently enacted and has proposed companion regulations to the California Consumer Privacy Act, or CCPA, which went into effect January 1, 2020. The CCPA creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide certain disclosures to consumers about its data collection, use and sharing practices, and to provide affected California residents with ways to opt-out of certain sales or transfers of personal information. The California State Attorney General commenced enforcement actions against violators beginning July 1, 2020. While there is currently an exception for protected health information that is subject to HIPAA and clinical trial regulations, other records and information we maintain on our customers may be subject to the CCPA.

Additionally, a new California ballot initiative, the California Privacy Rights Act, or CPRA, was passed in November 2020. Effective starting on January 1, 2023, the CPRA imposes additional obligations on companies covered by the legislation and will significantly modify the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information. The CPRA also creates a new state agency that will be vested with authority to implement and enforce the CCPA and the CPRA. The effects of the CCPA and the CPRA are potentially significant and may require us to modify our

data collection or processing practices and policies and to incur substantial costs and expenses in an effort to comply and increase our potential exposure to regulatory enforcement and/or litigation.

Certain other state laws impose similar privacy obligations, and we also expect that more states may enact legislation similar to the CCPA, which provides consumers with new privacy rights and increases the privacy and security obligations of entities handling certain personal information of such consumers. The CCPA has prompted a number of proposals for new federal and state-level privacy legislation. Such proposed legislation, if enacted, may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs and/or changes in business practices and policies.

In addition, on March 2, 2021, Virginia enacted the Consumer Data Protection Act, or the CDPA. The CDPA will become effective January 1, 2023. The CDPA will regulate how businesses (which the CDPA refers to as “controllers”) collect and share personal information. While the CDPA incorporates many similar concepts of the CCPA and CPRA, there are also several key differences in the scope, application and enforcement of the law that will change the operational practices of controllers. The new law will impact how controllers collect and process personal sensitive data, conduct data protection assessments, transfer personal data to affiliates and respond to consumer rights requests.

Also, on July 8, 2021, Colorado’s governor signed the Colorado Privacy Act, or CPA, into law. The CPA will become effective July 1, 2023. The CPA is rather similar to Virginia’s CPDA but also contains additional requirements. The new measure applies to companies conducting business in Colorado or who produce or deliver commercial products or services intentionally targeted to residents of the state that either: (1) control or process the personal data of at least 100,000 consumers during a calendar year; or (2) derive revenue or receive a discount on the price of goods or services from the sale of personal data and process or control the personal data of at least 25,000 consumers.

Where state laws are more protective than HIPAA, we must comply with the state laws we are subject to, in addition to HIPAA. In certain cases, it may be necessary to modify our planned operations and procedures to comply with these more stringent state laws. Not only may some of these state laws impose fines and penalties upon violators, but also some, unlike HIPAA, may afford private rights of action to individuals who believe their personal information has been misused. In addition, state laws are changing rapidly, and there is discussion of a new federal privacy law or federal breach notification law, to which we may be subject.

Furthermore, certain health privacy laws, data breach notification laws, consumer protection laws and genetic testing laws may apply directly to our operations and/or those of our collaborators and may impose restrictions on our collection, use and dissemination of individuals' health information. Patients about whom we or our collaborators may obtain health information, as well as the providers who may share this information with us, may have statutory or contractual rights that limit our ability to use and disclose the information. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend and could result in adverse publicity that could harm our business.

Because the interpretation and application of many privacy and data protection laws (including the GDPR), commercial frameworks, and standards are uncertain, it is possible that these laws, frameworks, and standards may be interpreted and applied in a manner that is inconsistent with our existing data management practices and policies. If so, in addition to the possibility of fines, lawsuits, breach of contract claims, and other claims and penalties, we could be required to fundamentally change our business activities and practices or modify our solutions, which could have an adverse effect on our business. Any inability to adequately address privacy and security concerns, even if unfounded, or comply with applicable privacy and security or data security laws, regulations, and policies, could result in additional cost and liability to us, damage our reputation, inhibit our ability to conduct trials, and adversely affect our business.

If we or third-party CMOs, CROs or other contractors or consultants fail to comply with applicable federal, state/provincial or local regulatory requirements, we could be subject to a range of regulatory actions that could affect our or our contractors' ability to develop and commercialize our therapeutic candidates and could harm or prevent sales of any affected therapeutics that we are able to commercialize, or could substantially increase the costs and expenses of developing, commercializing and marketing our therapeutics. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business. Increasing use of social media could give rise to liability, breaches of data security or reputational damage.

Additionally, we are subject to other state and foreign equivalents of each of the healthcare and privacy laws described above, among others, some of which may be broader in scope and may apply regardless of the payor.

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

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

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

***If the market opportunities for etavopivat and our other current and future product candidates are smaller than we believe they are, our revenue may be adversely affected, and our business may suffer. Moreover, because the target patient populations we are seeking to treat are small, we must be able to successfully identify patients and capture a significant market share to achieve profitability and growth.***

We focus our research and product development on treatments for rare hematologic diseases and cancers. The prevalence of SCD is approximately 100,000 individuals in the U.S. and approximately 30,000 individuals in France, Germany, Italy, Spain and the United Kingdom collectively. Similarly, the prevalence of beta thalassemia is estimated to be approximately 20,000 individuals across the U.S. and Europe and approximately 300,000 patients globally. Given the small number of patients who have the diseases that we are targeting, it is critical to our ability to grow and become profitable that we continue to successfully identify patients with these rare diseases. Our projections of both the number of people who have these diseases, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, surveys of clinics, patient foundations or market research that we conducted, and may prove to be incorrect or contain errors. New studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. The effort to identify

patients with diseases we seek to treat is in early stages, and we cannot accurately predict the number of patients for whom treatment might be possible. Further, even if we obtain significant market share for etavopivat and any of our other current or future product candidates, because the potential target populations are very small, we may never achieve profitability despite obtaining such significant market share.

Our target patient populations are relatively small, and there are currently limited standard of care treatments directed at SCD. As a result, the pricing and reimbursement of etavopivat and any other product candidates we may develop, if approved, is uncertain, but must be adequate to support commercial infrastructure. If we are unable to obtain adequate levels of reimbursement, our ability to successfully market and sell etavopivat and any of our other current or future product candidates will be adversely affected.

**Risks Related to Our Dependence on Third Parties**

***We rely, and expect to continue to rely, on third parties to conduct our ongoing and planned clinical trials for our current and future product candidates. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain marketing approval for or commercialize our current and potential future product candidates and our business could be substantially harmed.***

We do not have the ability to independently conduct clinical trials. We rely on medical institutions, clinical investigators, contract laboratories, and other third parties, including collaboration partners, to conduct or otherwise support our clinical trials for etavopivat and expect to rely on them when we begin clinical trials for FT-7051 and other current or future product candidates. We rely heavily on these parties for execution of clinical trials and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on CROs will not relieve us of our regulatory responsibilities. For any violations of laws and regulations during the conduct of our clinical trials, we could be subject to untitled and warning letters or enforcement action that may include civil penalties up to and including criminal prosecution.

We and any third parties that we contract with are required to comply with regulations and requirements, including GCP, for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial patients are adequately informed of the potential risks of participating in clinical trials and their rights are protected. These regulations are enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for any drugs in clinical development. The FDA enforces GCP requirements through periodic inspections of clinical trial sponsors, principal investigators and trial sites. If we or the third parties we contract with fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our current or future clinical trials will comply with GCP. In addition, our clinical trials must be conducted with current or future product candidates produced under cGMP regulations. Our failure or the failure of third parties that we contract with to comply with these regulations may require us to repeat some aspects of a specific, or an entire, clinical trial, which would delay the marketing approval process and could also subject us to enforcement action. We also are required to register certain ongoing clinical trials and provide certain information, including information relating to the trial's protocol, on a government-sponsored database, ClinicalTrials.gov, within specific timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Although we intend to design the clinical trials for our current or future product candidates or be involved in the design when other parties sponsor the trials, we anticipate that third parties will conduct all of our clinical trials. As a result, many important aspects of our clinical development, including their conduct, timing and response to the ongoing COVID-19 pandemic, will be outside of our direct control. Our reliance on third parties to conduct future clinical trials will also result in less direct control over the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may:

- have staffing difficulties;
- fail to comply with contractual obligations;
- experience regulatory compliance issues; and
- form relationships with other entities, some of which may be our competitors.

These factors may materially adversely affect the willingness or ability of third parties to conduct our clinical trials and may subject us to unexpected cost increases that are beyond our control. If our CROs do not perform clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development, marketing approval and commercialization of our current or future product candidates may be delayed, we may not be able to obtain marketing approval and commercialize our current or future product candidates, or our development programs may be materially and irreversibly harmed. If we are unable to rely on clinical data collected by our CROs, we could be required to repeat, extend the duration of, or increase the size of any of our clinical trials, and this could significantly delay commercialization and require significantly greater expenditures.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs on commercially reasonable terms, or at all. If our CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain are compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any clinical trials such CROs are associated with may be extended, delayed or terminated, and we may not

be able to obtain marketing approval for or successfully commercialize our current or future product candidates. As a result, we believe that our financial results and the commercial prospects for our current or future product candidates in the subject indication would be harmed, our costs could increase and our ability to generate revenue could be delayed.

***The third parties upon whom we rely for the supply of the active pharmaceutical ingredient, drug product and drug substance used in our product candidates are limited in number, and the loss of any of these suppliers could significantly harm our business.***

The active pharmaceutical ingredient, or API, drug product and drug substance used in our product candidates are supplied to us from a small number of suppliers, and in some cases sole source suppliers. Our ability to successfully develop our current or future product candidates, and to ultimately supply our commercial drugs in quantities sufficient to meet the market demand, depends in part on our ability to obtain the API, drug product and drug substance for these drugs in accordance with regulatory requirements and in sufficient quantities for commercialization and clinical testing. We do not currently have arrangements in place for a redundant or second-source supply of all API, drug product or drug substance in the event any of our current suppliers of such API, drug product and drug substance cease their operations for any reason.

For all of our current or future product candidates, we intend to identify and qualify additional manufacturers to provide such API, drug product and drug substance prior to submission of an NDA to the FDA and/or an MAA to the EMA. We are not certain, however, that our single-source and dual-source suppliers will be able to meet our demand for their products, either because of the nature of our agreements with those suppliers, our limited experience with those suppliers or our relative importance as a customer to those suppliers. It may be difficult for us to assess their ability to timely meet our demand in the future based on past performance. While our suppliers have generally met our demand for their products on a timely basis in the past, they may subordinate our needs in the future to their other customers.

Establishing additional or replacement suppliers for the API, drug product and drug substance used in our current or future product candidates, if required, may not be accomplished quickly. If we are able to find a replacement supplier, such replacement supplier would need to be qualified and may require additional regulatory approval, which could result in further delay. While we seek to maintain adequate inventory of the API, drug product and drug substance used in our current or future product candidates, any interruption or delay in the supply of components or materials, or our inability to obtain such API, drug product and drug substance from alternate sources at acceptable prices in a timely manner could impede, delay, limit or prevent our development efforts, which could harm our business, results of operations, financial condition and prospects.

***Our success is dependent on our executive management team's ability to successfully pursue business development, strategic partnerships and investment opportunities as our company matures. We may also form or seek strategic alliances or acquisitions or enter into additional collaboration and licensing arrangements in the future, and we may not realize the benefits of such collaborations, alliances, acquisitions or licensing arrangements.***

We have entered into licensing arrangements with Boehringer Ingelheim and Celgene Corporation, now Bristol-Myers Squibb Company, and may in the future form or seek strategic alliances or acquisitions, create joint ventures, or enter into additional collaboration and licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our current product candidates and any future product candidates that we may develop. For example, in March 2020, we sold select hit discovery capabilities and related assets to Valo Health, Inc. that aims to increase the efficiency of medicine development using computational-enabled capabilities. Under the deal terms, we received an upfront cash payment, additional cash installment payments and equity in Valo Health, Inc. as consideration. We are also eligible to receive low single digit future royalties on the aggregate net sales of any products that bind to a target in certain identified target classes, on a product-by-product and country-by-country basis during the periods of time commencing at the time of the first commercial sale of such product in such country, until the later of (i) the expiration of certain related patents and (ii) ten years after such first commercial sale.

Going forward, we continue to plan to seek a strategic partner for the further development and potential commercialization of olutasidenib. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business.

In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or acquisition or other alternative arrangements for our current or future product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our current or future product candidates as having the requisite potential to demonstrate safety, potency, purity and efficacy and obtain marketing approval.

Further, collaborations involving our current or future product candidates, are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- successful transfer of information, data, or materials related to product candidates to collaborators to permit continued development and commercialization activities;
- collaborators may not pursue development and commercialization of our current or future product candidates or may elect not to continue or renew development or commercialization of our current or future product candidates based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our current or future product candidates;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our current or future product candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable current or future product candidates;
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property; and
- collaborators may not pay milestones and royalties due to us in a timely manner.

As a result, we may not be able to realize the benefit of our existing collaboration and licensing arrangements or any future strategic partnerships, acquisitions, or license arrangements we may enter, if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction, license, collaboration or other business development partnership, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new collaborations or strategic partnership agreements related to our current or future product candidates could delay the development and commercialization of our current or future product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

***Our manufacturing process needs to comply with FDA regulations relating to the quality and reliability of such processes. Any failure to comply with relevant regulations could result in delays in or termination of our clinical programs and suspension or withdrawal of any regulatory approvals.***

In order to produce our product candidates for clinical trials and our products, if any, for commercial purposes, either at our own facility or at a third-party's facility, we and our third-party vendors will need to comply with the FDA's cGMP regulations and guidelines. We may encounter difficulties in achieving compliance with quality control and quality assurance requirements and may experience shortages in qualified personnel. We are subject to inspections by the FDA and comparable foreign regulatory authorities to confirm compliance with applicable regulatory requirements. Any failure to follow cGMP or other regulatory requirements, including any failure to remedy the issues identified in the cGMP gap analysis, or delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our product candidate as a result of a failure of our facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our current or future product candidates, including leading to significant delays in the availability of our product candidates for our clinical trials or the termination of or suspension of a clinical trial, or the delay or prevention of a filing or approval of marketing applications for our current or future product candidates. Significant non-compliance could also result in the imposition of sanctions, including warning or untitled letters, fines, injunctions, civil penalties, failure of

regulatory authorities to grant marketing approvals for our current or future product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation and our business.

Since March 2020, when foreign and domestic inspections of facilities were largely placed on hold, the FDA has been working to resume routine surveillance, bioresearch monitoring and pre-approval inspections on a prioritized basis. Since April 2021, the FDA has conducted limited inspections and employed remote interactive evaluations, using risk management methods, to meet user fee commitments and goal dates Ongoing travel restrictions and other uncertainties continue to impact oversight operations both domestic and abroad and it is unclear when standard operational levels will resume. The FDA is continuing to complete mission-critical work, prioritize other higher-tiered inspectional needs (e.g., for-cause inspections), and carry out surveillance inspections using risk-based approaches for evaluating public health. Should FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be adequate, the agency has stated that it generally intends to issue, depending on the circumstances, a complete response letter or defer action on the application until an inspection can be completed. During the COVID-19 public health emergency, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the ongoing COVID-19 pandemic and may experience delays in their regulatory activities.

***If our third-party manufacturers use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.***

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical materials, by our third-party manufacturers. Our manufacturers are subject to federal, state and local laws and regulations in the U.S. governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

**Risks Related to Intellectual Property**

Risks Related to Maintaining Our Intellectual Property

***If we are unable to obtain and maintain patent and other intellectual property protection for our technology and product candidates or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology and drugs may be impaired.***

Our commercial success depends in part on our ability to obtain and maintain proprietary or intellectual property protection in the U.S. and other countries for our current or future product candidates, including our lead product candidate, etavopivat, our other product candidate, FT-7051, our proprietary compound library and other know-how. We seek to protect our proprietary and intellectual property position by, among other methods, filing patent applications in the U.S. and abroad related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary and intellectual property position.

We own patent applications related to our product candidates including our lead product candidate, etavopivat, and our other product candidate, FT-7051. The etavopivat compound is covered through at least March 2038 (not including any patent term extension, supplementary protection certificate, pediatric exclusivity, or other extension or data exclusivity) by granted patents in multiple jurisdictions including the U.S., Australia, the European Patent Office, China, Japan, and South Korea; and by patent applications pending in numerous jurisdictions including the U.S. and Canada. The FT-7051 compound is covered through at least June 2039 (not including any patent term extension, supplementary protection certificate, pediatric exclusivity, or other extension or data exclusivity) by our granted patents in the U.S., Europe and Japan, and by patent applications pending in numerous jurisdictions including the U.S., Japan, and the European Patent Office.

We also own patents and patent applications related to our isocitrate dehydrogenase 1 gene (IDH1) program (FT-2102, or also referred to as “olutasidenib”), and our fatty-acid synthase (FASN) programs (FT-8225 and FT-4101). The FT-2102 compound is covered through at least September 2035 (not including any patent term extension, supplementary protection certificate, pediatric exclusivity, or other extension or data exclusivity) by granted patents in the U.S., Europe, Japan, China and other countries. The FT-2102 drug product is covered through at least May 2039 (not including any patent term extension, supplementary protection certificate, pediatric exclusivity, or other extension or data exclusivity) by additional granted U.S. patents and pending applications. FT-2102 is also covered through at least May 2039 (not including any patent term extension, supplementary protection certificate, pediatric exclusivity, or other extension or data exclusivity) by granted U.S. patents and pending patent applications for the uses of FT-2102 in methods of treatment currently in clinical development. The FT-8225 compound is covered through at least October 2039 (not including any patent term extension, supplementary protection certificate, pediatric exclusivity, or other extension or data exclusivity) by an issued U.S. patent and by pending applications in the U.S., European Patent Office, and other countries. The FT-4101 compound is covered through at least March 2034 (not including any patent term extension, supplementary protection certificate, pediatric exclusivity, or other extension or data exclusivity) by granted patents in multiple jurisdictions including the U.S. and European Patent Office. We also own a European patent to FT-4101 for use in a method of treatment providing coverage through at least April 2037. In addition, we own certain FT-4101 pharmaceutical compositions that are covered through at least October 2039 (not including any patent term extension, supplementary protection certificate, pediatric exclusivity, or other extension or data exclusivity) by a granted U.S. patent and pending applications in several jurisdictions, including the U.S. and European Patent Office.

In addition, we own patents and patent applications expected to expire between 2034 and 2042 (if granted) protecting a variety of additional novel compounds discovered by our target discovery engine for multiple therapeutic targets including ubiquitin specific protease 1 (USP1), IDH1, CBP/p300 and others.

As of April 15, 2022, our patent portfolio covering these additional novel compounds discovered by our target discovery engine included more than 20 patent families. Patent term adjustments, SPC filings, and/or patent term extensions could result in later expiration dates in various countries, while terminal disclaimers could result in earlier expiration dates in the U.S.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation.

The degree of patent protection we require to successfully commercialize our current or future product candidates may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We cannot provide any assurances that any of our patents have, or that any of our pending patent applications that mature into issued patents will include, claims with a scope sufficient to protect etavopivat and FT-7051 or our other current or future product candidates. In addition, if the breadth or strength of protection provided by our patent applications or any patents we may own or in-license is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the U.S. For example, in jurisdictions outside the U.S., a license may not be enforceable unless all the owners of the intellectual property agree or consent to the license. Accordingly, any actual or purported co-owner of our patent rights could seek monetary or equitable relief requiring us to pay it compensation for, or refrain from, exploiting these patents due to such co-ownership. Furthermore, patents have a limited lifespan. In the U.S., and most other jurisdictions in which we have undertaken patent filings, the natural expiration of a patent is generally twenty years after it is filed, assuming all maintenance fees are paid. Various extensions may be available, on a jurisdiction-by-jurisdiction basis; however, the life of a patent, and thus the protection it affords, is limited. 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, patents we may own or in-license may not provide us with adequate and continuing patent protection sufficient to exclude others from commercializing drugs similar or identical to our current or future product candidates, including generic versions of such drugs.

Other parties may have developed technologies related or competitive to our own, and such parties may have filed or may file patent applications, or may have received or may receive patents, claiming inventions that may overlap or conflict with those claimed in our own patent applications or issued patents, with respect to either the same compounds, methods, formulations or other subject matter, in either case that we may rely upon to dominate our patent position in the market. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until at least 18 months after earliest priority date of patent filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in patents we may own or in-license patents or pending patent applications, or that we were the first to file for

patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights cannot be predicted with any certainty.

In addition, the patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. Further, with respect to certain pending patent applications covering our current or future product candidates, prosecution has yet to commence. Patent prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the relevant patent office(s) may be significantly narrowed by the time they issue, if they ever do. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or to third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

Even if we acquire patent protection that we expect should enable us to establish and/or maintain a competitive advantage, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the U.S. and abroad. We may become involved in post-grant proceedings such as opposition, derivation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others from whom we may in the future obtain licenses to such rights, in the U.S. Patent and Trademark Office, or USPTO, the European Patent Office, or EPO, or in other countries. In addition, we may be subject to third-party submissions to the USPTO, the EPO, or elsewhere, that may reduce the scope or preclude the granting of claims from our pending patent applications. Competitors may allege that they invented the inventions claimed in our issued patents or patent applications prior to us, or may file patent applications before we do. Competitors may also claim that we are infringing their patents and that we therefore cannot practice our technology as claimed under our patents or patent applications. Competitors may also contest our patents by showing an administrative patent authority or judge that the invention was not patent-eligible, was not original, was not novel, was obvious, and/or lacked inventive step, and/or that the patent application filing failed to meet relevant requirements relating to description, basis, enablement, and/or support; in litigation, a competitor could claim that our patents, if issued, are not valid or are unenforceable for a number of reasons. If a court or administrative patent authority agrees, we would lose our protection of those challenged patents.

An adverse determination in any such submission or proceeding may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and drugs, without payment to us, or could limit the duration of the patent protection covering our technology and current or future product candidates. Such challenges may also result in our inability to manufacture or commercialize our current or future product candidates without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

In addition, we may in the future be subject to claims by our former employees or consultants asserting an ownership right in our patents or patent applications, as a result of the work they performed on our behalf. Although we generally require all of our employees, consultants and advisors and any other third parties who have access to our proprietary know-how, information or technology to assign or grant similar rights to their inventions to us, we cannot be certain that we have executed such agreements with all parties who may have contributed to our intellectual property, nor can we be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy.

Even if they are unchallenged, our issued patents and our pending patent applications, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent patents we may own or in-license by developing similar or alternative technologies or drugs in a non-infringing manner. For example, a third-party may develop a competitive drug that provides benefits similar to one or more of our current or future product candidates but that has a different composition that falls outside the scope of our patent protection. If the patent protection provided by the patents and patent applications we hold or pursue with respect to our current or future product candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our current or future product candidates could be negatively affected, which would harm our business.

Furthermore, even if we are able to issue patents with claims of valuable scope in one or more jurisdictions, we may not be able to secure such claims in all relevant jurisdictions, or in a sufficient number to meaningfully reduce competition.

Our competitors may be able to develop and commercialize their products, including products identical to ours, in any jurisdiction in which we are unable to obtain, maintain, or enforce such patent claims.

***Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, deadlines, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated if we fail to comply with these requirements.***

The USPTO and foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and after issuance of any patent. In addition, periodic maintenance fees, renewal fees, annuity fees and/or various other government fees are required to be paid periodically. While an inadvertent lapse can in some cases be cured by payment of a late fee or by other means in accordance with the applicable rules, 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. Noncompliance events that could result in abandonment or lapse of a patent include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market with similar or identical products or platforms, which could have a material adverse effect on our business prospects and financial condition.

***If our trademarks and trade names for our products or company name are not adequately protected in one or more countries where we intend to market our products, we may delay the launch of product brand names, use different trademarks or tradenames in different countries, or face other potentially adverse consequences to building our product brand recognition.***

Our trademarks or trade names may be challenged, infringed, diluted, circumvented or declared generic or determined to be infringing on other marks. We intend to rely on both registration and common law protection for our trademarks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During the trademark registration process, we may receive Office Actions from the USPTO or from comparable agencies in foreign jurisdictions objecting to the registration of our trademark. Although we would be given an opportunity to respond to those objections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and/or to seek the cancellation of registered trademarks. Opposition or cancellation proceedings may be filed against our trademark applications or registrations, and our trademark applications or registrations may not survive such proceedings. If we are unable to obtain a registered trademark or establish name recognition based on our trademarks and trade names, we may not be able to compete effectively, and our business may be adversely affected.

***If we are unable to adequately protect and enforce our trade secrets, our business and competitive position would be harmed.***

In addition to the protection afforded by patents we may own or in-license, we seek to rely on trade secret protection, confidentiality agreements, and license agreements to protect proprietary know-how that may not be patentable, processes for which patents are difficult to enforce and any other elements of our product discovery and development processes that involve proprietary know-how, information, or technology that may not be covered by patents. Although we require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, trade secrets can be difficult to protect, and we have limited control over the protection of trade secrets used by our collaborators and suppliers. We cannot be certain that we have or will obtain these agreements in all circumstances, and we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary information.

Moreover, any of these parties might breach the agreements and intentionally or inadvertently disclose our trade secret information and we may not be able to obtain adequate remedies for such breaches. In addition, competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights and trade secrets to the same extent or in the same manner as the laws of the U.S. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the U.S. and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, financial condition, results of operations and future prospects.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. If we choose to go to court to stop a third-party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are

successful. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third-party, we would have no right to prevent them from using that technology or information to compete with us.

Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual or entity during the course of the party's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary technology by third parties. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. Although we require all of our employees to assign their inventions to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

***Intellectual property rights do not guarantee commercial success of current or future product candidates or other business activities. Numerous factors may limit any potential competitive advantage provided by our intellectual property rights.***

The degree of future protection afforded by our intellectual property rights, whether owned or in-licensed, is uncertain because intellectual property rights have limitations, and may not adequately protect our business, provide a barrier to entry against our competitors or potential competitors, or permit us to maintain our competitive advantage. Moreover, if a third-party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The following examples are illustrative:

- patent applications that we own or may in-license may not lead to issued patents;
- patents, should they issue, that we may own or in-license, may not provide us with any competitive advantages, may be narrowed in scope, or may be challenged and held invalid or unenforceable;
- others may be able to develop and/or practice technology, including compounds that are similar to the chemical compositions of our current or future product candidates, that is similar to our technology or aspects of our technology but that is not covered by the claims of any patents we may own or in-license, should any patents issue;
- third parties may compete with us in jurisdictions where we do not pursue and obtain patent protection;
- we, or our future licensors or collaborators, might not have been the first to make the inventions covered by a patent application that we own or may in-license;
- we, or our future licensors or collaborators, might not have been the first to file patent applications covering a particular invention;
- others may independently develop similar or alternative technologies without infringing, misappropriating or otherwise violating our intellectual property rights;
- our competitors might conduct research and development activities in the U.S. and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and may then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not be able to obtain and/or maintain necessary licenses on reasonable terms or at all;
- third parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights, or any rights at all, over that intellectual property;
- 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 trade secrets or know-how;
- we may not be able to maintain the confidentiality of our trade secrets or other proprietary information;
- we may not develop or in-license additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

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

***We may not obtain or grant licenses or sublicenses to intellectual property rights in all markets on equally or sufficiently favorable terms with third parties.***

It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties. The licensing 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. More 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 license such technology, or if we are forced to license such technology on unfavorable terms, our business could be materially harmed. If we are unable to obtain a necessary license, we may be unable to develop or commercialize the affected current or future product candidates, which could materially harm our business, and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. Any of the foregoing could harm our competitive position, business, financial condition, results of operations and prospects.

***Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our current or future product candidates.***

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Recent patent reform legislation in the U.S. and other countries, including the Leahy-Smith America Invents Act, or Leahy-Smith Act, signed into law on September 16, 2011, could increase those uncertainties and costs. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. In addition, the Leahy-Smith Act has transformed the U.S. patent system into a “first inventor to file” system. The first-inventor-to-file provisions, however, only became effective on March 16, 2013. Accordingly, it is not yet clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could make it more difficult to obtain patent protection for our inventions and increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could harm our business, results of operations and financial condition.

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. Additionally, there have been recent proposals for additional changes to the patent laws of the U.S. and other countries that, if adopted, could impact our ability to obtain patent protection for our proprietary technology or our ability to enforce our proprietary technology. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, 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 patents that we might obtain in the future.

Risks Related to Intellectual Property Litigation

***We may initiate, become a defendant in, or otherwise become party to lawsuits to protect or enforce our intellectual property rights, which could be expensive, time-consuming and unsuccessful.***

Competitors may infringe any patents we may own or in-license. In addition, any patents we may own or in-license also may become involved in inventorship, priority, validity or unenforceability disputes. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, in an infringement proceeding, a court may decide that one or more of any patents we may own or in-license is not valid or is unenforceable or that the other party’s use of our technology that may be patented falls under the safe harbor to patent infringement under 35 U.S.C. §271(e)(1). There is also the risk that, even if the validity of these patents is upheld, the court may refuse to stop the other party from using the technology at issue on the grounds that any

patents we may own or in-license do not cover the technology in question or that such third-party's activities do not infringe our patent applications or any patents we may own or in-license. An adverse result in any litigation or defense proceedings could put one or more of any patents we may own or in-license at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, patient support 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 and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

Depending upon the timing, duration and specifics of FDA marketing approval of our current or future product candidates, one or more of the U.S. patents we own or license may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. Different laws govern the extension of patents on approved pharmaceutical products in Europe and other jurisdictions. However, we may not be granted a patent extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. For example, we may not be granted an extension in the U.S. if all of our patents covering an approved product expire more than fourteen years from the date of NDA approval for a product covered by those patents. 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 ability to generate revenues could be materially adversely affected.

Post-grant proceedings provoked by third-parties or brought by the USPTO may be necessary to determine the validity or priority of inventions with respect to our patent applications or any patents we may own or in-license. These proceedings are expensive and an unfavorable outcome could result in a loss of our current patent rights and 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. In addition to potential USPTO post-grant proceedings, we may become a party to patent opposition proceedings in the EPO, or similar proceedings in other foreign patent offices or courts where our patents may be challenged. The costs of these proceedings could be substantial, and may result in a loss of scope of some claims or a loss of the entire patent. An unfavorable result in a post-grant challenge proceeding may result in the loss of our right to exclude others from practicing one or more of our inventions in the relevant country or jurisdiction, which could have a material adverse effect on our business. Litigation or post-grant proceedings within patent offices may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the U.S.

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 during this type of litigation. In addition, there could 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 substantial adverse effect on the price of our common stock.

We may not be able to detect infringement against any patents we may own or in-license. Even if we detect infringement by a third-party of any patents we may own or in-license, we may choose not to pursue litigation against or settlement with the third-party. If we later sue such third-party for patent infringement, the third-party may have certain legal defenses available to it, which otherwise would not be available except for the delay between when the infringement was first detected and when the suit was brought. Such legal defenses may make it impossible for us to enforce any patents we may own or in-license against such third-party.

***Intellectual property litigation and administrative patent office patent validity challenges in one or more countries could cause us to spend substantial resources and distract our personnel from their normal responsibilities.***

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims 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, patient support or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. As noted above, 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, including compromising 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 collaborations that would help us commercialize our current or future product candidates, if approved. Any of the foregoing events would harm our business, financial condition, results of operations and prospects.

***We may be subject to damages or settlement costs resulting from claims that we or our employees have violated the intellectual property rights of third parties, or are in breach of our agreements. We may be accused of, allege or otherwise become party to lawsuits or disputes alleging wrongful disclosure of third-party confidential information by us or by another party, including current or former employees, contractors or consultants. In addition to diverting attention and resources to such disputes, such disputes could adversely impact our business reputation and/or protection of our proprietary technology.***

The intellectual property landscape relevant to our product candidates and programs is crowded, and third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business. Our commercial success depends upon our ability to develop, manufacture, market and sell our current and future product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including derivation, interference, reexamination, *inter partes* review and post grant review proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We or any of our current or future licensors or strategic partners may be party to, exposed to, or threatened with, future adversarial proceedings or litigation by third parties having patent or other intellectual property rights alleging that our current or future product candidates and/or proprietary technologies infringe, misappropriate or otherwise violate their intellectual property rights. We cannot assure you that our current or future product candidates and other technologies that we have developed, are developing or may develop in the future do not or will not infringe, misappropriate or otherwise violate existing or future patents or other intellectual property rights owned by third parties. For example, many of our employees were previously employed at other biotechnology or pharmaceutical companies. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's former employer. We may also be subject to claims that patents and applications we have filed to protect inventions of our employees, consultants and advisors, even those related to one or more of our current or future product candidates, are rightfully owned by their former or concurrent employer. Litigation may be necessary to defend against these claims.

While certain activities related to development and clinical testing of our current or future product candidates may be subject to safe harbor of patent infringement under 35 U.S.C. §271(e)(1), upon receiving FDA approval for such candidates we or any of our future licensors or strategic partners may immediately become party to, exposed to, or threatened with, future adversarial proceedings or litigation by third parties having patent or other intellectual property rights alleging that such product candidates infringe, misappropriate or otherwise violate their intellectual property rights. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our current or future product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our current or future product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our current or future product candidates, technologies or methods.

If a third-party claims that we infringe, misappropriate or otherwise violate its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement, misappropriation and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our business and may impact our reputation;

- substantial damages for infringement, misappropriation or other violations, which we may have to pay if a court decides that the product candidate or technology at issue infringes, misappropriates or violates the third-party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;
- a court prohibiting us from developing, manufacturing, marketing or selling our current or future product candidates, including etavopivat, FT-7051, olutasidenib and FT-4101, or from using our proprietary technologies, unless the third-party licenses its product rights to us, which it is not required to do, on commercially reasonable terms or at all;
- if a license is available from a third-party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights for our products, or the license to us may be non-exclusive, which would permit third parties to use the same intellectual property to compete with us;
- redesigning our current or future product candidates or processes so they do not infringe, misappropriate or violate third-party intellectual property rights, which may not be possible or may require substantial monetary expenditures and time; and
- 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.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition, results of operations or prospects.

We may choose to challenge the patentability of claims in a third-party's U.S. patent by requesting that the USPTO review the patent claims in an *ex-parte* re-exam, *inter partes* review or post-grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third-party's patent in patent opposition proceedings in the EPO, or other foreign patent office. The costs of these opposition proceedings could be substantial and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent office then we may be exposed to litigation by a third-party alleging that the patent may be infringed by our current or future product candidates or proprietary technologies.

Third parties may assert that we are employing their proprietary technology without authorization. Patents issued in the U.S. by law enjoy a presumption of validity that can be rebutted in U.S. courts only with evidence that is "clear and convincing," a heightened standard of proof. There may be issued third-party patents of which we are currently unaware with claims to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our current or future product candidates. Patent applications can take many years to issue. In addition, because some patent applications in the U.S. may be maintained in secrecy until the patents are issued, patent applications in the U.S. and many foreign jurisdictions are typically not published until 18 months after their earliest priority filing date, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications covering our current or future product candidates or technology. If any such patent applications issue as patents, and if such patents have priority over our patent applications or patents we may own or in-license, we may be required to obtain rights to such patents owned by third parties which may not be available on commercially reasonable terms or at all, or may only be available on a non-exclusive basis. There may be currently pending third-party patent applications which may later result in issued patents that our current or future product candidates may infringe. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to our current or future product candidates or other technologies, could be found to be infringed by our current or future product candidates or other technologies. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Moreover, we may fail to identify relevant patents or incorrectly conclude that a patent is invalid, not enforceable, exhausted, or not infringed by our activities. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our current or future product candidates, molecules used in or formed during the manufacturing process, or any final product itself, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to

a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our current or future product candidates may be impaired or delayed, which could in turn significantly harm our business. Even if we obtain a license, it may be nonexclusive, thereby giving our competitors access to the same technologies licensed to us.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our current or future product candidates. Defense of these claims, regardless of their merit, could involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement, misappropriation or other violation against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need or may choose to obtain licenses from third parties to advance our research or allow commercialization of our current or future product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our current or future product candidates, which could harm our business significantly.

***We may be unable to obtain patent or other intellectual property protection for our current or future product candidates or our future products, if any, in all jurisdictions throughout the world, and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.***

We may not be able to pursue patent coverage of our current or future product candidates in all countries. Filing, prosecuting and defending patents on current or future product candidates in all countries throughout the world would be prohibitively expensive, and intellectual property rights in some countries outside the U.S. can be less extensive than those in the U.S. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling or importing products made using our inventions in and into the U.S. 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 where enforcement is not as strong as that in the U.S. These products may compete with our current or future product candidates and in jurisdictions where we do not have any issued patents our patent applications or other intellectual property rights may not be effective or sufficient to prevent them from competing. Much of our patent portfolio is at the very early stage. We will need to decide whether and in which jurisdictions to pursue protection for the various inventions in our portfolio prior to applicable deadlines.

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

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

Risks Related to Our Third-Party Intellectual Property Obligations

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

We may from time to time be party to license and collaboration agreements with third parties to advance our research or allow commercialization of current or future product candidates. Such agreements may impose numerous obligations, such as development, diligence, payment, commercialization, funding, milestone, royalty, sublicensing, insurance, patent

prosecution, enforcement and other obligations on us and may require us to meet development timelines, or to exercise commercially reasonable efforts to develop and commercialize licensed products, in order to maintain the licenses. In spite of our best efforts, our licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing or limiting our ability to develop and commercialize products and technologies covered by these license agreements.

Any termination of these licenses, or if the underlying patents fail to provide the intended exclusivity, could result in the loss of significant rights and could harm our ability to commercialize our current or future product candidates, and competitors or other third parties would have the freedom to seek regulatory approval of, and to market, products identical to ours and we may be required to cease our development and commercialization of certain of our current or future product candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

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

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe, misappropriate or otherwise violate intellectual property rights of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our current or future product candidates, and what activities satisfy those diligence obligations;
- the priority of invention of any patented technology; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our future licensors and us and our partners.

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

***Any granted patents we may own or in-license covering our current or future product candidates or other valuable technology could be narrowed or found invalid or unenforceable if challenged in court or before administrative bodies in the U.S. or abroad, including the USPTO and the EPO. A patent asserted in a judicial court could be found invalid or unenforceable during the enforcement proceeding. Administrative or judicial proceedings challenging the validity of our patents or individual patent claims could take months or years to resolve.***

If we or our licensors or strategic partners initiate legal proceedings against a third-party to enforce a patent covering one of our current or future product candidates, the defendant could counterclaim that the patent covering our product candidate, as applicable, is invalid and/or unenforceable. In patent litigation in the U.S., defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third-party can assert invalidity or unenforceability of a patent. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of patentable subject matter, lack of written description, lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, in the process of obtaining the patent during patent prosecution. Third parties may also raise similar claims before administrative bodies in the U.S. or abroad, even outside the context of litigation. Such mechanisms include re-examination, *inter partes* review, post grant review and equivalent proceedings in foreign jurisdictions (such as opposition proceedings). Such proceedings could result in revocation or amendment to our patent applications or any patents we may own or in-license in such a way that they no longer cover our current or future product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, any rights we may have from our patent applications or any patents we may own or in-license, allow third parties to commercialize our current or future product candidates or other technologies 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, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our or our future licensors' priority of invention or other features of patentability with respect to our patent applications and any patents we may own or in-license. 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 current or future product candidates and other technologies. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we or our future licensing partners and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, or if we are otherwise unable to adequately protect our rights, we would lose at least part, and perhaps all, of the patent protection on our current or future product candidates. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and current or future 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. If we are unsuccessful in any such proceeding or other priority or inventorship dispute, we may be required to obtain and maintain licenses from third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes. Such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture, and commercialization of one or more of the current or future product candidates we may develop. The loss of exclusivity or the narrowing of our patent application claims could limit our ability to stop others from using or commercializing similar or identical technology and products. Any of the foregoing could have a material adverse effect on our business, results of operations, financial condition and prospects.

***We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might subject us to infringement claims or adversely affect our ability to develop and market our current or future product candidates.***

We cannot guarantee that any of our or our licensors' patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending patent application in the U.S. and abroad that is relevant to or necessary for the commercialization of our current or future product candidates in any jurisdiction. For example, U.S. patent applications filed before November 29, 2000 and certain U.S. patent applications filed after that date that will not be filed outside the U.S. remain confidential until patents issue. As mentioned above, patent applications in the U.S. and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our current or future product candidates could have been filed by third parties without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our current or future product candidates or the use of our current or future product candidates. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our current or future product candidates. We may incorrectly determine that our current or future product candidates are not covered by a third-party patent or may incorrectly predict whether a third-party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the U.S. or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our current or future product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our current or future product candidates.

If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, which may be significant, we may be temporarily or permanently prohibited from commercializing any of our current or future product candidates that are held to be infringing. We might, if possible, also be forced to redesign current or future product candidates so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business and could adversely affect our business, financial condition, results of operations and prospects.

**Risks Related to Employee Matters, Managing Growth and Other Risks Related to Our Business**

Risks Related to Our Operations

***We or the third parties upon whom we depend may be adversely affected by natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.***

Our current operations are located in Massachusetts. Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, health epidemics, including any potential effects from the current global spread of COVID-19, power shortage, telecommunication failure or other natural or man-made accidents or incidents that result in us being unable to fully utilize our facilities, or the manufacturing facilities of our third-party contract manufacturers, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates or interruption of our business operations. Natural disasters, the severity and frequency of which may be amplified by global climate change, or health epidemics, such as the COVID-19 pandemic, could further disrupt our operations, and have a material and adverse effect on our business, financial condition, results of operations and prospects. For example, we have instituted a temporary work from home policy for non-essential office personnel and it is possible that this could have a negative impact on the execution of our business plans and operations. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our research facilities or the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure our investors 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 may be harmed. Any business interruption may have a material and adverse effect on our business, financial condition, results of operations and prospects.

***Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.***

We are highly dependent on the research and development, clinical and business development expertise of Frank D. Lee, our President and Chief Executive Officer, Patrick Kelly, M.D., our SVP, Chief Medical Officer, Todd Shegog, our SVP, Chief Financial Officer, David N. Cook, Ph.D., our SVP, Chief Scientific Officer, Jeannette Potts, Ph.D, J.D., our SVP, General Counsel, Mary E. Wadlinger, our SVP, Corporate Affairs and Chief Human Resources Officer, John E. Bishop, Ph.D. our SPV, Chief Technology Officer, and Brian Lesser, our SVP, Commercial, as well as the other principal members of our management, scientific and clinical team. Although we have entered into employment letter agreements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain “key person” insurance for any of our executives or other employees. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize drugs. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. Failure to succeed in clinical trials may make it more challenging to recruit and retain qualified personnel.

***We will need to develop and expand our company, and we may encounter difficulties in managing this development and expansion, which could disrupt our operations.***

As of April 15, 2022, we had 176 full-time employees. To manage our anticipated development and expansion, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue

to recruit and train additional qualified personnel. Also, our management may need to divert a disproportionate amount of its attention away from its day-to-day activities and devote a substantial amount of time to managing these development activities. Due to our limited resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The physical expansion of our operations may lead to significant costs and may divert financial resources from other projects, such as the development of our current or future product candidates. If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than expected, our ability to generate or increase our revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our current or future product candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage the future development and expansion of our company.

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

As widely reported, global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability, including most recently in connection with the global outbreak of COVID-19 and the Russian invasion of Ukraine. Furthermore, inflation rates in the U.S. have recently increased to levels not seen in decades. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive.

Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay, scale back or discontinue the development and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

Furthermore, our stock price has declined and may further decline due in part to the volatility of the stock market and the general economic downturn.

***Our employees, principal investigators, CROs and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.***

We are exposed to the risk that our employees, principal investigators, CROs and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate the regulations of the FDA and other regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities; healthcare fraud and abuse laws and regulations in the U.S. and abroad; or laws that require the reporting of financial information or data accurately. In particular, sales, marketing, patient support and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. In connection with our IPO, we adopted a code of conduct applicable to all of our employees, but it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Because of the breadth of these laws and the narrowness of the statutory

exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant criminal, civil and administrative sanctions including monetary penalties, damages, fines, disgorgement, individual imprisonment, and exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, reputational harm, and we may be required to curtail or restructure our operations, any of which could adversely affect our ability to operate our business and our results of operations.

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the EU. The provision of benefits or advantages to physicians is governed by the national anti-bribery laws of EU Member States, such as the U.K. Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment. Payments made to physicians in certain EU Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

The collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the EU, including personal health data, is subject to the GDPR, which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EU, including the U.S., and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Compliance with the GDPR is a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities.

Risks Related to Tax

***Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.***

Under Sections 382 and 383 of the Code, if a corporation undergoes an "ownership change" (generally defined as a greater than 50 percentage points (by value) in the ownership of its equity over a three-year period), the corporation's ability to use its pre-change tax attributes to offset its post-change income may be limited. We have experienced such ownership changes in the past, and we may experience ownership changes in the future or subsequent shifts in our stock ownership, some of which are outside our control. As of December 31, 2021, we had state NOLs of approximately $282.0 million and federal NOLs of approximately $150.6 million. The federal NOLs do not expire but the state NOLs expire if not utilized before 2041. In addition, we had federal and state research and development tax credit carryforwards of approximately $40.7 million and $5.1 million, respectively. Our ability to utilize these NOLs and tax credit carryforwards may be limited by any "ownership change" as described above that have occurred in prior years or that may occur in the future. If we undergo future ownership changes, many of which may be outside of our control, our ability to utilize our NOLs and tax credit carryforwards could be further limited by Sections 382 and 383 of the Code. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing NOLs could expire or otherwise become unavailable to offset future income tax liabilities. Additionally, our NOLs and tax credit

carryforwards could be limited under state law. For these reasons, even if we attain profitability, we may be unable to use a material portion of our NOLs and other tax attributes.

***Changes in tax law could adversely affect our business and financial condition.***

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service, or IRS, and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future.

For example, the Tax Cuts and Jobs Act, or the TCJA, was enacted in 2017 and significantly reformed the Internal Revenue Code of 1986, as amended, or the Code. The TCJA, among other things, contained significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for net interest expense to 30% of adjusted taxable income (except for certain small businesses), limitation of the deduction for net operating losses, or NOLs, from taxable years beginning after December 31, 2017 to 80% of current year taxable income and elimination of NOL carrybacks generated in taxable years ending after December 31, 2017 (though any such NOLs may be carried forward indefinitely) immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Additionally, on March 27, 2020, former President Trump signed into law the Coronavirus Aid, Relief, and Economic Security Act, the CARES Act, which, among other things, suspends the 80% limitation on the deduction for NOLs arising in taxable years beginning before January 1, 2021, permits a 5-year carryback of NOLs arising in taxable years beginning after December 31, 2017 and before January 1, 2021, and generally modifies the limitation on the deduction for net interest expense to 50% of adjusted taxable income for taxable years beginning in 2019 and 2020. It cannot be predicted whether, when, in what form or with what effective dates tax laws, regulations and rulings may be enacted, promulgated or issued, which could result in an increase in our or our shareholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law.

Risks Related to Internal Controls

***If we fail to establish and maintain proper and effective internal control over financial reporting, our operating results and our ability to operate our business could be harmed.***

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be re-evaluated frequently. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. We have completed the process of documenting, reviewing and improving our internal controls and procedures for compliance with Section 404 of the Sarbanes-Oxley Act, which requires annual management assessment of the effectiveness of our internal control over financial reporting. We continue to recruit additional finance and accounting personnel with certain skill sets that we need as a public company.

Implementing any appropriate changes to our internal controls may distract our officers and employees, entail substantial costs to modify our existing processes, and take significant time to complete. These changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and harm our business. In addition, investors' perceptions that our internal controls are inadequate or that we are unable to produce accurate financial statements on a timely basis may harm our stock price and make it more difficult for us to effectively market and sell our service to new and existing customers.

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

We are subject to certain reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

Risks Related to Cybersecurity

***We may be unable to adequately protect our information systems from cyberattacks, which could result in the disclosure of confidential or proprietary information, including personal data, damage our reputation, and subject us to significant financial and legal exposure.***

We rely on information technology systems that we or our third-party providers operate to process, transmit and store electronic information in our day-to-day operations. In connection with our product discovery efforts, we may collect and use a variety of personal data, such as name, mailing address, email addresses, phone number and clinical trial information. A successful cyberattack could result in the theft or destruction of intellectual property, data or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations. In addition to such risks, the adoption of new technologies may also increase our exposure to cybersecurity breaches and failures. Further, having a significant portion of our workforce working from home for extended periods of time due to the COVID-19 pandemic puts us at greater risk of cybersecurity attacks. Cyberattacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyberattacks could include wrongful conduct by hostile foreign governments, industrial espionage, wire fraud and other forms of cyber fraud, the deployment of harmful malware, denial-of-service, social engineering fraud or other means to threaten data security, confidentiality, integrity and availability. A successful cyberattack could cause serious negative consequences for us, including, without limitation, the disruption of operations, the misappropriation of confidential business information, including financial information, trade secrets, financial loss and the disclosure of corporate strategic plans. Although we devote resources to protect our information systems, we realize that cyberattacks are a threat, and there can be no assurance that our efforts will prevent information security breaches that would result in business, legal, financial or reputational harm to us, or would have a material adverse effect on our results of operations and financial condition. Any failure to prevent or mitigate security breaches or improper access to, use of, or disclosure of our clinical data or patients' personal data could result in significant liability under state (e.g., state breach notification laws), federal (e.g., HIPAA, as amended by HITECH), and international law (e.g., the EU General Data Protection Regulation, or GDPR) and may cause a material adverse impact to our reputation, affect our ability to use collected data, conduct new studies and potentially disrupt our business.

We rely on our third-party providers to implement effective security measures and identify and correct for any such failures, deficiencies or breaches. We also rely on our employees and consultants to safeguard their security credentials and follow our policies and procedures regarding use and access of computers and other devices that may contain our sensitive information. If we or our third-party providers fail to maintain or protect our information technology systems and data integrity effectively or fail to anticipate, plan for or manage significant disruptions to our information technology systems, we or our third-party providers could have difficulty preventing, detecting and controlling such cyber-attacks and any such attacks could result in losses described above as well as disputes with employees, physicians, patients and our partners, regulatory sanctions or penalties, increases in operating expenses, expenses or lost revenues or other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition, prospects and cash flows. Any failure by us or such third parties to prevent or mitigate security breaches or improper access to or disclosure of such information could have similarly adverse consequences for us. If we are unable to prevent or mitigate the impact of such security or data privacy breaches, we could be exposed to litigation and governmental investigations, which could lead to a potential disruption to our business.

***Our internal computer systems, or those of our third-party CROs, collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our current or future product candidates' development programs.***

We are increasingly dependent upon information technology systems, infrastructure, and data to operate our business. In the ordinary course of business, we collect, store, and transmit large amounts of confidential information, including, but not limited to, intellectual property, proprietary business information, and personal information. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We also have outsourced elements of our operations to third parties, and as a result we manage a number of third-party vendors who may or could have access to our confidential information. Our third-party collaborators also have access to large amounts of confidential information relating to our operations, including our research and development efforts. The size and complexity of our information technology systems, and those of third-party vendors and collaborators, and the large amounts of confidential information stored on those systems, make such systems potentially vulnerable to service interruptions or systems failures, or to security breaches from inadvertent or intentional actions by our employees, third-party vendors, and/or business partners, or from cyber-attacks by malicious third parties.

Despite the implementation of security measures, our internal computer systems and those of our third-party CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such system failure, accident, or security breach to date, if such an event were to occur and cause interruptions in our operations, it

could result in a material disruption of our programs. For example, the loss of preclinical or clinical trial data for our current or future product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications or other data or applications relating to our technology or current or future product candidates, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and the further development of our current or future product candidates could be delayed.

**Risks Related to Ownership of our Common Stock**

Risks Related to Investments in Our Securities

***The price of our common stock may be volatile and fluctuate substantially, and you could lose all or part of your investment.***

Our stock price is likely to be volatile. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price for our common stock may be influenced by many factors, including:

- the success of competitive drugs or technologies;
- results of clinical trials of our current or future product candidates or those of our competitors;
- regulatory or legal developments in the U.S. and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our current or future product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional current or future product candidates or drugs;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this “Risk Factors” section.

The novel coronavirus has been spreading rapidly around the world since December 2019 and has negatively affected the stock market and investor sentiment. The price of our common stock may be disproportionately affected as investors may favor traditional profit-making industries and companies during the times of market uncertainty and instability.

***Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or current or future product candidates.***

Until such time, if ever, as we can generate substantial drug revenues, we expect to finance our cash needs through a combination of private and public equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that materially adversely affect your rights as a common stockholder. Debt financing, if available, would increase our fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

On July 26, 2021, we filed a Registration Statement on Form S-3 with the SEC, which was automatically declared effective on July 26, 2021 (File No. 333-258174), as amended by Post-Effective Amendment No. 1 and Post-Effective Amendment No. 2 on Form S-3 filed on March 1, 2022, in relation to the registration of up to $400.0 million of common stock, preferred stock, debt securities, warrants and units or any combination thereof, or the 2021 Shelf. We also simultaneously entered into a Sales Agreement, or the Sales Agreement, with SVB Leerink LLC, or the Sales Agent, to provide for the offering, issuance and sale of up to an aggregate amount of $200.0 million of our common stock from time to time in “at-the-market” offerings, with $150.0 million of common stock currently registered under the 2021 Shelf, and subject to the limitations thereof. We will pay to the Sales Agent cash commissions of up to 3.0% of the gross proceeds of sales of common stock under the Sales Agreement. Sales of a substantial number of shares of our outstanding common stock in the public market could occur at any time. As of the date of this Quarterly Report on Form 10-Q, we have not

made any sales of our common stock under the Sales Agreement. Sales under the Sales Agreement, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock. Persons who were our stockholders prior to our IPO continue to hold a substantial number of shares of our common stock that many of them are now able to sell in the public market. Significant portions of these shares are held by a relatively small number of stockholders. Sales by our stockholders of a substantial number of shares, or the expectation that such sales may occur, could significantly reduce the market price of our common stock.

If we raise funds through additional collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property, future revenue streams, research programs or current or future product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, scale back or discontinue the development and commercialization of one or more of our product candidates, delay our pursuit of potential in-licenses or acquisitions or grant rights to develop and market current or future product candidates that we would otherwise prefer to develop and market ourselves.

***The dual class structure of our common stock may limit your ability to influence corporate matters and may limit your visibility with respect to certain transactions.***

The dual class structure of our common stock may also limit your ability to influence corporate matters. Holders of our common stock are entitled to one vote per share, while holders of our non-voting common stock are not entitled to any votes. Nonetheless, each share of our non-voting common stock may be converted at any time into one share of our common stock at the option of its holder by providing written notice to us, subject to the limitations provided for in our amended and restated certificate of incorporation. As of March 31, 2022, entities affiliated with or managed by certain of our stockholders hold an aggregate of 2,505,825 shares of our non-voting common stock. At any time, upon written notice, these entities could convert a portion of these shares of non-voting common stock into up to an aggregate of 4.99% of our shares of common stock. Upon 61 days' prior written notice, these entities could convert all of their respective shares of non-voting common stock into shares of common stock, which would result in such entities holding approximately 5.3% of the voting power of our outstanding common stock as of March 31, 2022. Consequently, if holders of our non-voting common stock exercise their option to make this conversion, this will have the effect of increasing the relative voting power of those prior holders of our non-voting common stock, and correspondingly decreasing the voting power of the holders of our common stock, which may limit your ability to influence corporate matters. Additionally, stockholders who hold, in the aggregate, more than 10% of our common stock and non-voting common stock, but 10% or less of our common stock, and are not otherwise a company insider, may not be required to report changes in their ownership due to transactions in our non-voting common stock pursuant to Section 16(a) of the Exchange Act, and may not be subject to the short-swing profit provisions of Section 16(b) of the Exchange Act.

***If securities analysts do not publish or cease publishing research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.***

The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us or our business. We do not have control over these analysts. There can be no assurance that existing analysts will continue to provide research coverage or that new analysts will begin to provide research coverage. Although we have obtained analyst coverage, if one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

***As of January 1, 2022, we are no longer an "emerging growth company" or a "smaller reporting company" and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies are no longer available to us.***

As of June 30, 2021, the market value of our common stock that was held by non-affiliates exceeded $700 million, so effective as of January 1, 2022, we became a large accelerated filer. As a large accelerated filer, we no longer qualify as an emerging growth company or smaller reporting company and we are no longer able to avail ourselves of the reduced disclosure requirements available to smaller reporting companies.

As a large accelerated filer, we are subject to certain disclosure requirements that are applicable to other public companies that have not been applicable to us as an emerging growth company. These requirements include:

- compliance with the auditor attestation requirements in the assessment of our internal control over financial reporting;

- compliance with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation;
- full disclosure obligations regarding executive compensation; and
- compliance with the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

In addition, as a large accelerated filer, we must comply with certain disclosure requirements that were not previously applicable to us as a smaller reporting companies. Similar to emerging growth companies, smaller reporting companies are able to provide simplified executive compensation disclosure and have certain other reduced disclosure obligations, including, among other things, being required to provide only two years of audited financial statements and not being required to provide selected financial data, supplemental financial information or risk factors. For our SEC filings on the periods following January 1, 2022, we are no longer able to rely on these reduced requirements.

***We will continue to incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.***

As a public company, and particularly as we are no longer an emerging growth company or smaller reporting company, we continue to incur significant legal, accounting and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which requires, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act of 2002, as amended, or Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and The Nasdaq Global Market to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas, such as “say on pay” and proxy access. Recent legislation permits emerging growth companies to implement many of these requirements over a longer period and up to five years from the pricing of its initial public offering; however, we can no longer take advantage of this legislation because we are not an emerging growth company. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to continue to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The increased costs will decrease our net income or increase our net loss and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

***Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.***

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

***Because of potential volatility in our trading price and trading volume, we may incur significant costs from class action securities litigation.***

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

Risks Related to Our Charter and Bylaws

***Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control, which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.***

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the board of directors acting pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, or DGCL, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These antitakeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

***Our bylaws designate certain courts as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.***

Our bylaws provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any state law claims for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers and employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL, our amended and restated certificate of incorporation or our bylaws (in each case, as they may be amended from time to time) or (iv) any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein; provided, however, that this exclusive forum provision will not apply to any causes of action arising under the Securities Act of 1933, as amended, or the Securities Act, or the Exchange Act. Our bylaws further provide that, unless we consent in writing to an alternative forum, the United States District Court for the District of Massachusetts will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. We have chosen the United States District Court for the District of Massachusetts as the exclusive forum for such Securities Act causes of action because our principal executive offices are located in Watertown, Massachusetts. In addition, our amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the foregoing provisions. We recognize that the forum selection clause in our bylaws may impose additional litigation costs on stockholders in pursuing any such claims, particularly if the stockholders do not reside in or near the State of Delaware or the Commonwealth of Massachusetts, as applicable. Additionally, the forum selection clause in our bylaws may limit our stockholders' ability to bring a claim in a forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. The Court of Chancery of the State of Delaware or the United States District Court for the District of Massachusetts may also reach different judgments

or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.**

None.

**Item 3. Defaults Upon Senior Securities.**

None.

**Item 4. Mine Safety Disclosures.**

Not applicable.

**Item 5. Other Information.**

None.

**Item 6. Exhibits.**

| Exhibit Number | Description |
|---|---|
| 3.1 | Second Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-39333) filed with the SEC on June 23, 2020) |
| 3.2 | Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-39333) filed with the SEC on June 23, 2020) |
| 31.1* | Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 31.2* | Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 32.1+ | Certifications of Principal Executive Officer and Principle Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 101.INS | Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its 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 (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101.*) |

* Filed herewith.
+ The certifications furnished in Exhibit 32.1 hereto are deemed to be furnished with this Quarterly Report on Form 10-Q and will not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference.

**SIGNATURES**

Pursuant to the requirements 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.

FORMA THERAPEUTICS HOLDINGS, INC

Date: May 6, 2022

By: /s/ Frank D. Lee

**Frank D. Lee**

**President and Chief Executive Officer**

**(Principal Executive Officer)**

Date: May 6, 2022

By: /s/ Todd Shegog

**Todd Shegog**

**Chief Financial Officer**
**(Principal Financial and Accounting Officer)**

**Exhibit 31.1**

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO RULE 13a-14(a) / RULE 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED**

I, Frank D. Lee, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Forma Therapeutics Holdings, 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(s) 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(s) 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.

/s/ Frank D. Lee
**Frank D. Lee**
**President and Chief Executive Officer**
**(Principal Executive Officer)**

Dated: May 6, 2022

**Exhibit 31.2**

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO RULE 13a-14(a) / RULE 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED**

I, Todd Shegog, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Forma Therapeutics Holdings, 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(s) 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(s) 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.

/s/ Todd Shegog
**Todd Shegog**
**Chief Financial Officer**
**(Principal Financial and Accounting Officer)**

Dated: May 6, 2022

**Exhibit 32.1**

**CERTIFICATIONS OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Forma Therapeutics Holdings, Inc. (the "Company") for the quarter ended March 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned hereby certify, pursuant to 18 U.S.C. Section 1350, that, to the best of their knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

/s/ Frank D. Lee

**Frank D. Lee**
**President and Chief Executive Officer**
**(Principal Executive Officer)**

Dated: May 6, 2022

/s/ Todd Shegog

**Todd Shegog**
**Chief Financial Officer**
**(Principal Financial and Accounting Officer)**

Dated: May 6, 2022