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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 June 30, 2022

OR

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

For the transition period from _____ to
Commission File No. 001-38944

Akero Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**81-5266573**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

601 Gateway Boulevard, Suite 350
South San Francisco, CA 94080
(650) 487-6488

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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 $0.0001 per share	AKRO	The Nasdaq Global Select 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 July 29, 2022, the registrant had 37,571,426 shares of common stock, $0.0001 par value per share, outstanding.

SUMMARY OF THE MATERIAL RISKS ASSOCIATED WITH OUR BUSINESS

Our business is subject to numerous risks and uncertainties, including those described in Part II, Item 1A. “Risk Factors” in this Quarterly Report on Form 10-Q. The principal risks and uncertainties affecting our business includes:

- Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control, including difficulties in identifying patients with nonalcoholic steatohepatitis (“NASH”), significant competition for recruiting such patients in clinical trials, and restrictions on patients and investigators related to the ongoing coronavirus disease (“COVID-19”) pandemic.
- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than us.
- Failures or delays in the commencement or completion of, or ambiguous or negative results from our planned clinical trials of our product candidates could result in increased costs to us and could delay, prevent, or limit our ability to generate revenue and continue our business.
- Clinical development is uncertain and our clinical trials for efruxifermin (“EFX”) and any future product candidates may experience delays, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all, which would have an adverse effect on our business.
- We rely and will continue to rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval of or commercialize any potential product candidates.
- The manufacture of our product candidates is complex and we may encounter difficulties in production. If we or any of our third-party manufacturers encounter such difficulties, or fail to meet rigorously enforced regulatory standards, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.
- We are heavily dependent on the success of EFX, our only product candidate.
- If we fail to develop and successfully commercialize other product candidates, our business and future prospects may be harmed and our business will be more vulnerable to any problems that we encounter in developing and commercializing our product candidate.
- We may develop EFX, and potentially future product candidates, in combination with other therapies, which exposes us to additional risks.
- If we are not successful in discovering, developing, receiving regulatory approval for and commercializing EFX and any future product candidates, our ability to expand our business and achieve our strategic objectives would be impaired.
- We may be required to make significant payments under our license agreement for EFX.
- The regulatory approval processes of the U.S. Food and Drug Administration (the “FDA”) and comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable. Our inability to obtain regulatory approval for EFX or any future product candidate would substantially harm our business.
- Even if we are able to obtain regulatory approvals for our product candidate or any future product candidates, if they exhibit harmful side effects after approval, our regulatory approvals could be revoked or otherwise negatively impacted, and we could be subject to costly and damaging product liability claims.
- Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse, transparency and other healthcare laws and regulations, which, if violated, could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.
- We have incurred significant losses since our inception and we expect to incur losses for the foreseeable future.
- We currently have a limited operating history, have not generated any revenue to date, and may never become profitable.
- We will require additional capital to finance our operations, which may not be available to us on acceptable terms, or at all. As a result, we may not complete the development and commercialization of our product candidate or develop any future product candidates.
- Business interruptions resulting from the ongoing COVID-19 pandemic or similar public health crises, as well as from geopolitical and military conflict such as the ongoing warfare in Ukraine, could cause a disruption of the development of our product candidates and adversely impact our business.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These statements involve risks, uncertainties, and other factors that may cause actual results, levels of activity, performance, or achievements to be materially different from the information expressed or implied by these forward-looking statements. All statements, other than statements of historical facts, contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management and expected market growth are forward-looking statements. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

These forward-looking statements include, among other things, statements about:

- the success, cost and timing of our product development activities and clinical trials, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available, and our research and development programs;
- our ability to successfully conduct and complete our ongoing Phase 2b clinical trial of EFX in patients with NASH who have F2 or F3 fibrosis, known as the HARMONY study, including the ability to obtain data and maintain our expected timelines during the ongoing COVID-19 pandemic;
- our ability to complete enrollment in our ongoing Phase 2b clinical trial of EFX in patients with NASH who have cirrhosis (F4 fibrosis, compensated), known as the SYMMETRY study, including the ability to obtain data and maintain our expected timelines during the ongoing COVID-19 pandemic;
- our ability to complete enrollment in an ongoing expansion cohort of the SYMMETRY study, known as Cohort D, which is evaluating EFX in patients who have both Type 2 Diabetes, or T2D, and NASH, and are being treated with GLP-1 therapeutics to manage their T2D;
- the potential for COVID-19 or other pandemic, epidemic or outbreak of an infectious disease, to disrupt our business plans, product development activities, ongoing clinical trials, including the timing and enrollment of patients, the health of our employees and the strength of our supply chain;
- our ability to advance any product candidate into or successfully complete any clinical trial;
- our ability to successfully manufacture our product candidates for future clinical trials or for commercial use, if approved;
- the potential for our identified research priorities to advance our technologies;
- our ability to obtain and maintain regulatory approval, if obtained, of EFX or any future product candidates, and any related restrictions, limitations and/or warnings in the label of an approved product candidate;
- the ability to license additional intellectual property relating to any future product candidates and to comply with our existing license agreement;
- our ability to commercialize our products in light of the intellectual property rights of others;
- the success of competing therapies that are or become available;
- our ability to obtain funding for our operations, including funding necessary to complete further development and commercialization of our product candidates;
- the commercialization of our product candidates, if approved;
- our plans to research, develop and commercialize our product candidates;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- future agreements with third parties in connection with the commercialization of our product candidates and any other approved product;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- the rate and degree of market acceptance of our product candidates;
- regulatory developments in the United States and foreign countries;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- our ability to attract and retain key scientific or management personnel;

- the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- the impact of laws and regulations; and
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Quarterly Report on Form 10-Q, particularly in the "Risk Factors" section, that could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, collaborations, joint ventures or investments that we may make or into which we may enter.

You should read this Quarterly Report on Form 10-Q and the documents that we reference herein and have filed or incorporated by reference as exhibits hereto completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

NOTE REGARDING TRADEMARKS

Akero Therapeutics, Inc. is the owner of the AKERO trademark, as well as certain other trademarks, including design versions of some of these trademarks. The symbols ™ and ® are not used in connection with the presentation of these trademarks in this report and their absence does not indicate a lack of trademark rights. Certain other trademarks used in this report are the property of third-party trademark owners and may be presented with or without trademark references.

All brand names or trademarks appearing in this report are the property of their respective owners. Unless the context requires otherwise, references in this report to "Akero," the "Company," "we," "us" and "our" refer to Akero Therapeutics, Inc. and its subsidiary.

PART I—FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements

Akero Therapeutics, Inc.

Condensed Consolidated Balance Sheets
(In thousands, except share and per share amounts)
(Unaudited)

	June 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 177,727	$ 150,483
Short-term marketable securities	2,998	37,775
Prepaid expenses and other current assets	3,422	5,324
Total current assets	184,147	193,582
Property and equipment, net	68	90
Right of use asset	1,352	1,459
Other assets, noncurrent	108	417
Total assets	$ 185,675	$ 195,548
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 6,877	$ 6,706
Accrued expenses and other current liabilities	19,820	18,422
Total current liabilities	26,697	25,128
Loan payable, noncurrent	9,366	—
Warrant liability	41	—
Operating lease liability, noncurrent	1,199	1,311
Total liabilities	37,303	26,439
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Common stock, $0.0001 par value, 150,000,000 shares authorized as of June 30, 2022 and December 31, 2021; 37,570,326 and 34,900,727 shares issued and outstanding as of June 30, 2022 and December 31, 2021, respectively	4	4
Additional paid-in capital	512,107	479,436
Accumulated other comprehensive loss	(3)	(27)
Accumulated deficit	(363,736)	(310,304)
Total stockholders' equity	148,372	169,109
Total liabilities and stockholders' equity	$ 185,675	$ 195,548

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

Akero Therapeutics, Inc.

Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 21,363	$ 23,976	$ 41,877	$ 34,578
General and administrative	6,231	4,990	11,768	9,516
Total operating expenses	27,594	28,966	53,645	44,094
Loss from operations	(27,594)	(28,966)	(53,645)	(44,094)
Interest expense	(53)	—	(53)	—
Other income	244	33	266	71
Net loss	(27,403)	(28,933)	(53,432)	(44,023)
Net unrealized gain (loss) on short-term marketable securities	27	(7)	24	(6)
Comprehensive loss	$ (27,376)	$ (28,940)	$ (53,408)	$ (44,029)
Net loss per common share, basic and diluted	$ (0.77)	$ (0.83)	$ (1.52)	$ (1.27)
Weighted-average number of shares used in computing net loss per common share, basic and diluted	35,383,685	34,814,631	35,195,638	34,779,647

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

Akero Therapeutics, Inc.

Condensed Consolidated Statements of Stockholders' Equity (Deficit)
(In thousands, except share amounts)
(Unaudited)

	Common Stock		Additional Paid-In-Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount				
Balances at December 31, 2021	34,900,727	$ 4	$ 479,436	$ (27)	$ (310,304)	$ 169,109
Exercise of stock options	122,208	—	147	—	—	147
Stock-based compensation expense	—	—	3,311	—	—	3,311
Net unrealized loss on short-term marketable securities	—	—	—	(3)	—	(3)
Net loss	—	—	—	—	(26,029)	(26,029)
Balances at March 31, 2022	35,022,935	$ 4	$ 482,894	$ (30)	$ (336,333)	$ 146,535
Issuance of common stock pursuant to ESPP purchases	22,139	—	178	—	—	178
Issuance of common stock pursuant to equity investment by Pfizer, net of issuance costs	2,525,252	—	24,647	—	—	24,647
Vested warrants issued pursuant to loan agreement	—	—	227	—	—	227
Stock-based compensation expense	—	—	4,161	—	—	4,161
Net unrealized gain on short-term marketable securities	—	—	—	27	—	27
Net loss	—	—	—	—	(27,403)	(27,403)
Balances at June 30, 2022	37,570,326	$ 4	$ 512,107	$ (3)	$ (363,736)	$ 148,372
Balances at December 31, 2020	34,741,649	$ 4	$ 468,238	$ (3)	$ (209,527)	$ 258,712
Exercise of stock options	28,670	—	24	—	—	24
Vesting of restricted stock	—	—	9	—	—	9
Stock-based compensation expense	—	—	2,364	—	—	2,364
Net unrealized gain on short-term marketable securities	—	—	—	1	—	1
Net loss	—	—	—	—	(15,090)	(15,090)
Balances at March 31, 2021	34,770,319	$ 4	$ 470,635	$ (2)	$ (224,617)	$ 246,020
Exercise of stock options	60,333	—	393	—	—	393
Vesting of restricted stock	—	—	9	—	—	9
Issuance of common stock pursuant to ESPP purchases	10,130	—	215	—	—	215
Stock-based compensation expense	—	—	2,436	—	—	2,436
Net unrealized loss on short-term marketable securities	—	—	—	(7)	—	(7)
Net loss	—	—	—	—	(28,933)	(28,933)
Balances at June 30, 2021	34,840,782	$ 4	$ 473,688	$ (9)	$ (253,550)	$ 220,133

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

Akero Therapeutics, Inc.

Condensed Consolidated Statements of Cash Flows
(In thousands)
(Unaudited)

	Six Months Ended June 30,	
	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (53,432)	$ (44,023)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	7,472	4,800
Depreciation	22	21
Non-cash lease expense	107	100
Net amortization of premiums and discounts on short-term investments	181	303
Amortization of debt issuance costs and discount	16	—
Unrealized foreign exchange gain and loss	(24)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	2,122	(2,848)
Accounts payable	145	(1,121)
Accrued expenses and other current liabilities	1,105	4,475
Operating lease liability	(99)	(87)
Net cash used in operating activities	(42,385)	(38,380)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of short-term marketable securities	—	(31,654)
Proceeds from maturities of short-term marketable securities	34,620	40,000
Net cash provided by investing activities	34,620	8,346
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from the exercise of stock options	147	417
Proceeds from the issuance of common stock pursuant to employee stock purchase plan purchases	178	215
Proceeds from the issuance of common stock pursuant to private offering	25,000	—
Proceeds from loan payable	10,000	—
Payment of loan payable issuance costs	(255)	—
Payment of deferred offering costs	(61)	(342)
Net cash provided by financing activities	35,009	290
Net increase (decrease) in cash, cash equivalents and restricted cash	27,244	(29,744)
Cash, cash equivalents and restricted cash at the beginning of the period	150,591	187,390
Cash, cash equivalents and restricted cash at the end of the period	$ 177,835	$ 157,646
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING INFORMATION:		
Change in net unrealizable gain (loss) on marketable securities	$ 24	$ (6)
Deferred offering costs reclassified to additional paid-in equity	$ 150	$ —
Equity issuance costs included in accounts payable and accrued expenses and other current liabilities	$ 202	$ —
Debt issuance costs included in accounts payable and accrued expenses and other current liabilities	$ 127	$ —
Deferred offering costs included in accounts payable and accrued expenses and other current liabilities	$ 15	$ 123

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

Akero Therapeutics, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements
(Amounts in thousands, except share and per share data)

1. Nature of the business and basis of presentation

Akero Therapeutics, Inc., together with its wholly owned subsidiary Akero Securities Corporation, ("Akero" or the "Company") is a clinical-stage company dedicated to developing transformational treatments for patients with serious metabolic diseases marked by high unmet medical need, including non-alcoholic steatohepatitis, or NASH, a disease without any approved therapies. NASH is a severe form of nonalcoholic fatty liver disease, or NAFLD, characterized by inflammation and fibrosis in the liver that can progress to cirrhosis, liver failure, cancer and death. The Company's lead product candidate is efruxifermin, or EFX, an analog of fibroblast growth factor 21, or FGF21, which is an endogenously expressed hormone that protects against cellular stress and regulates metabolism of lipids, carbohydrates and proteins throughout the body. EFX is currently being evaluated in two Phase 2b clinical trials in patients with biopsy-confirmed NASH: the HARMONY study in patients with pre-cirrhotic NASH (F2-F3 fibrosis) and the SYMMETRY study in cirrhotic patients (F4 fibrosis, compensated). The SYMMETRY study includes an expansion cohort, known as Cohort D, evaluating the safety and tolerability of EFX compared to placebo when added to an existing GLP-1 receptor agonist in patients with pre-cirrhotic NASH (F1-F3 fibrosis) and Type 2 diabetes. The Company previously conducted a Phase 2a clinical trial, the BALANCED study, to evaluate EFX in the treatment of patients with biopsy-confirmed NASH. The main portion of this study in patients with pre-cirrhotic NASH (F1-F3 fibrosis) showed EFX's potential to reverse fibrosis, resolve NASH, improve liver health, improve glycemic control and improve lipoprotein profile. An expansion cohort in patients with cirrhotic NASH (F4 fibrosis), compensated) showed comparable results. Based on clinical data to date, the Company believes EFX has the potential to be a highly differentiated, best-in-class FGF21 analog and promising NASH monotherapy, if approved.

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, completion and success of clinical testing, development by competitors of new technological innovations, compliance with governmental regulations, dependence on key personnel and protection of proprietary technology and the ability to secure additional capital to fund operations. EFX will require extensive clinical testing prior to regulatory approval and commercialization. These efforts require significant amounts of additional capital, adequate personnel, and infrastructure and extensive compliance-reporting capabilities. Even if the Company's drug development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

Basis of presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") and include the accounts of the Company after elimination of all intercompany accounts and transactions. All adjustments necessary for the fair presentation of the Company's condensed consolidated financial statements for the periods presented have been reflected.

Liquidity

In accordance with Accounting Standards Update ("ASU") No. 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (Subtopic 205-40)*, the Company has evaluated whether there are certain conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the consolidated financial statements are issued.

Since its inception, the Company has funded its operations primarily with proceeds from sales of redeemable convertible preferred stock and with proceeds from its initial public offering ("IPO") in June 2019, a follow-on public offering of its common stock in July 2020 and most recently through a term loan and a registered direct offering in June 2022. The Company has incurred recurring losses since its inception, including net losses of $53,432 and $44,023 for the six months ended June 30, 2022 and 2021, respectively, and net losses of $100,777 and $79,207 for the years ended December 31, 2021 and 2020, respectively. In addition, as of June 30, 2022, the Company had an accumulated deficit of

$363,736. The Company expects to continue to generate operating losses for the foreseeable future. As of August 5, 2022, the issuance date of these condensed consolidated financial statements, the Company expects that its existing cash, cash equivalents and short-term marketable securities of $180,725 as of June 30, 2022, will be sufficient to fund its operating expenses and capital expenditure requirements for at least 12 months from the issuance date of these condensed consolidated financial statements. The Company expects that it will require additional funding to complete the clinical development of EFX, commercialize EFX, if it receives regulatory approval, and pursue in-licenses or acquisitions of other product candidates.

If the Company is unable to obtain funding, the Company will be forced to delay, reduce or eliminate some or all of its research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect its business prospects, or the Company may be unable to continue operations. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all.

2. Summary of significant accounting policies

Unaudited interim financial statements

The accompanying unaudited condensed consolidated financial statements have been prepared by the Company in accordance with GAAP for interim financial reporting and as required by Regulation S-X, Rule 10-01. The unaudited condensed consolidated financial statements have been prepared on the same basis as the Company's audited annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for a fair statement of the Company's condensed consolidated balance sheet as of June 30, 2022, the condensed consolidated statements of operations and comprehensive loss for the three and six months ended June 30, 2022 and 2021, the condensed consolidated statement of stockholders' equity (deficit) as of June 30, 2022 and the condensed consolidated statements of cash flows for the six months ended June 30, 2022. The financial data and other information disclosed in these notes related to the three and six months ended June 30, 2022 and 2021 are unaudited. The results for the three and six months ended June 30, 2022 are not necessarily indicative of results to be expected for the year ending December 31, 2022, any other interim periods, or any future year or period.

Use of estimates

The preparation of the Company's condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements, and the reported amounts of expenses during the reporting period. Significant estimates and assumptions reflected in these condensed consolidated financial statements include, but are not limited to, the recognition of research and development expenses, stock-based compensation expense, warrant liabilities and the valuation allowance for deferred tax assets. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates when there are changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ from those estimates.

Cash and cash equivalents

The Company considers all highly liquid investments with original maturities of three months or less at the time of purchase to be cash equivalents. Cash equivalents consist primarily of amounts invested in money market accounts.

Akero Therapeutics, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements
(Amounts in thousands, except share and per share data)

Short-term marketable securities

The Company invests in short-term marketable securities, primarily money market funds, commercial paper, U.S. treasury securities and corporate debt securities. The Company continually evaluates the credit ratings of its investment portfolio and underlying securities. The Company invests in accordance with its investment policy and invests at the date of purchase in securities with high ratings from top rating agencies. The Company classifies its short-term marketable securities as available-for-sale securities and reports them at fair value in short-term marketable securities on the condensed consolidated balance sheets with related unrealized gains and losses included within accumulated other comprehensive gain (loss) on the condensed consolidated balance sheets. The amortized cost of marketable securities is adjusted for amortization of premiums and accretion of discounts to maturity, which is included in other income on the condensed consolidated statements of operations and comprehensive loss. When the fair value is below the amortized cost of a marketable security, the Company reviews and determines whether the impairment is due to credit-related factors or noncredit-related factors. The credit-related impairment amount is recognized in other income on the condensed consolidated statements of operations and comprehensive loss, with a corresponding allowance for credit losses account in the condensed consolidated balance sheet. Subsequent improvements in expected credit losses are recognized as a reversal of an amount in the allowance account. If the Company has the intent to sell the security or it is more likely than not that the Company will be required to sell the security prior to recovery of its amortized cost basis, then the allowance for the credit loss is written-off and the excess of the amortized cost basis of the asset over its fair value is recorded in the condensed consolidated statements of operations. There were no credit losses recorded during the periods ended June 30, 2022 and December 31, 2021.

Restricted cash

As of June 30, 2022 and December 31, 2021, the Company was required to maintain a separate cash balance of $108 for the benefit of the landlord in connection with the Company’s Gateway office space lease in South San Francisco, California (the “Gateway Lease”), which is classified within other assets (non-current) on the condensed consolidated balance sheets (see Note 12).

Concentrations of credit risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash, cash equivalents and short-term marketable securities. Periodically, the Company maintains deposits in accredited financial institutions in excess of federally insured limits. The Company deposits its cash investments in financial institutions that it believes have high credit quality and has not experienced any losses on such accounts and does not believe it is exposed to any unusual credit risk beyond the normal credit risk associated with commercial banking relationships. At June 30, 2022 and December 31, 2021, all of the Company's cash, cash equivalents and short-term investments were held at one accredited financial institution.

Leases

The Company determines whether an arrangement is or contains a lease at inception by assessing whether the arrangement contains an identified asset and whether the Company has the right to control the identified asset. Right-of-use, or ROU, assets represent the Company’s right to use an underlying asset for the lease term and lease liabilities represent the Company’s obligation to make lease payments arising from the lease. Lease liabilities are recognized at the lease commencement date based on the present value of future lease payments over the lease term. ROU assets are based on the measurement of the lease liability and are further adjusted by any lease payments made prior to or on lease commencement, lease incentives received and initial direct costs incurred, as applicable. The Company has elected to not recognize leases with a lease term of one year or less on its balance sheet. Operating lease costs included in the measurement of the lease are recognized on a straight-line basis over the lease term. Variable lease costs are expensed as incurred as an operating expense.

Akero Therapeutics, Inc.

Notes to Unaudited Condensed Consolidated Financial Statements
(Amounts in thousands, except share and per share data)

The Company determines the lease classification and the present value of future lease payments at the time of the lease commencement using an incremental borrowing rate that it estimates based upon the Company's credit risk and term of the lease. The interest rate implicit in lease contracts has not historically been readily determinable and the Company must therefore use the appropriate incremental borrowing rate to measure its leases. To estimate the incremental borrowing rate, a credit rating applicable to the Company is estimated using a synthetic credit rating analysis since the Company does not currently have a rating agency-based credit rating.

Research and development costs

Research and development costs are expensed as incurred. Research and development expenses consist of costs incurred to discover, research and develop drug candidates, including personnel expenses, stock-based compensation expense, third-party license fees and external costs including fees paid to consultants, contract manufacturing organizations, or CMOs, and clinical research organizations, or CROs, in connection with drug product manufacturing, nonclinical studies and clinical trials, and other related clinical trial fees, such as for investigator grants, patient screening, laboratory work, clinical trial database management, clinical trial material management and statistical compilation and analysis. Non-refundable prepayments for goods or services that will be used or rendered for future research and development activities are recorded as prepaid expenses. Such amounts are recognized as an expense as the goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered or the services rendered.

Costs incurred in obtaining technology licenses are charged immediately to research and development expense if the technology licensed has not reached technological feasibility and has no alternative future uses.

Research contract costs and accruals

The Company has entered into various research and development and other agreements with commercial firms, researchers and others for provisions of goods and services. These agreements are generally cancelable, and the related costs are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research and development costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies or clinical trials, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ materially from the Company's estimates.

Stock-based compensation

The Company measures all stock-based awards granted to employees and nonemployees based on the fair value on the date of the grant and recognizes compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award, on a straight-line basis. The Company recognizes stock-based compensation expense for awards that contain performance-based conditions using the accelerated attribution method when management determines it is probable that the performance condition will be satisfied. The Company accounts for forfeitures as they occur.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model, which requires inputs based on certain subjective assumptions, including the expected stock price volatility, the expected term of the option, the risk-free interest rate for a period that approximates the expected term of the option, and the Company's expected dividend yield. The Company went public in June 2019 and accordingly, lacks sufficient company-specific historical and implied volatility information for its shares traded in the public markets. Therefore, it estimates its expected share price volatility based on the historical volatility of publicly traded peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded share price. The expected term of the Company's stock options has been determined utilizing the "simplified"

method for awards that qualify as "plain-vanilla" options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends on common stock and does not expect to pay any cash dividends in the foreseeable future. The fair value of each common stock award is estimated on the date of grant based on the fair value of the Company's common stock on that same date.

Compensation expense for purchases under the Employee Stock Purchase Plan is recognized based on the fair value of the common stock estimated based on the closing price of our common stock as reported on the date of offering, less the purchase discount percentage provided for in the plan.

The Company classifies stock-based compensation expense in its condensed consolidated statement of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

Loan Payable

The Company initially reviews loan payables to identify the units of account for recognition purposes. The Company identifies the units of account by identifying each freestanding financial instrument included in the debt arrangement. For freestanding equity-linked financial instruments that are not in the form of shares, liability classification is used if the instrument embodies an obligation to repurchase the Company’s shares that may require the use of cash or other assets or the instrument may require the issuance of a variable number of the Company’s shares with a monetary value that is predominately based on a fixed value, based on variations in variables other than the fair value of the Company’s stock, or based on variations inversely related to the fair value of the Company’s stock. The Company will then review for embedded features within the debt instrument to evaluate whether the embedded features require bifurcation from the debt host instrument. Embedded features typically include conversion or exchange features, redemption features, or other embedded features. The identified embedded feature is bifurcated from the debt host instrument if the criteria in ASC 815-15-25-1 are met. Debt arrangements are classified on the consolidated balance sheet as current if the obligation of the debt arrangement is reasonably expected to be liquidated within 12 months. Loan payable is recorded net of debt discount which comprises issuance costs, customary closing and end of term charge or final fees, and the fair value of additional warrants issued in conjunction with the loan payable. Debt discount is amortized over the term of the loan payable using the effective interest method, and is recorded to interest expense on the consolidated statements of operations (see Note 6).

Warrant Liabilities

The Company accounts for warrants anticipated to be issued in the future under the Loan Agreement as liabilities and measures them at fair value using the Black-Scholes valuation model. The warrants are subject to remeasurement at each prospective balance sheet date, with any changes in the fair value recorded in the consolidated statements of operations.

Comprehensive loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity (deficit) that result from transactions and economic events other than those with stockholders. The Company’s comprehensive loss is comprised of net loss and changes in unrealized gains and losses on its short-term marketable securities.

Recently adopted accounting pronouncements

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments - Credit Losses (Topic 326) ("ASU 2016-13"), which introduced a new methodology for accounting for credit losses on financial instruments, including

available-for-sale debt securities. The Company adopted ASU 2016-03 as of January 1, 2021. For available-for-sale debt securities with unrealized losses, those losses are recognized as allowances rather than reductions in the amortized cost of the underlying security. The adoption of ASU 2016-03 did not have a material impact on the Company's condensed consolidated financial statements.

In August 2020, the FASB issued ASU No. 2020-06, “Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging— Contracts in Entity’s Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity’s Own Equity”, or ASU 2020-06. ASU 2020-06 simplifies the accounting for convertible instruments by eliminating the requirement to separate embedded conversion features from the host contract when the conversion features are not required to be accounted for as derivatives under Topic 815, Derivatives and Hedging, or that do not result in substantial premiums accounted for as paid-in capital. The Company adopted ASU 2020-06 on January 1, 2022, on a modified retrospective basis. The adoption of ASU 2020-06 did not have a material impact on the Company's condensed consolidated financial statements.

3. Fair value measurements

Certain assets and liabilities of the Company are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

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The following is a summary of our financial assets and liabilities measured at fair value on a recurring basis as of June 30, 2022 and December 31, 2021:

	June 30, 2022			
	Total	Level 1	Level 2	Level 3
Money market funds	$ 151,791	$ 151,791	$ —	$ —
Corporate debt securities	2,998	—	2,998	—
Total assets	$ 154,789	$ 151,791	$ 2,998	$ —
Warrant liabilities	$ 41	$ —	$ —	$ 41
Total liabilities	$ 41	$ —	$ —	$ 41

	December 31, 2021			
	Total	Level 1	Level 2	Level 3
Money market funds	$ 116,261	$ 116,261	$ —	$ —
Corporate debt securities	37,775	—	37,775	—
	$ 154,036	$ 116,261	$ 37,775	$ —

Corporate debt securities were valued by the Company using quoted prices in active markets for similar securities, which represent a Level 2 measurement within the fair value hierarchy.

The carrying values of the Company's prepaid expenses and other current assets, accounts payable and accrued expenses approximate their fair values due to the short-term nature of these assets and liabilities. During the six months ended June 30, 2022 and the twelve months ended December 31, 2021, there were no transfers between Level 1, Level 2 and Level 3.

The Loan Payable is classified as a Level 3 liability. As of June 30, 2022, the carrying value of the Loan Payable, excluding unamortized debt issuance costs, approximates its fair value due to the variable interest rate. The Company estimated the fair value of the warrant liabilities using the Black-Scholes model based on key assumption and inputs (see Note 6). The Company utilizes a probability assessment to estimate the likelihood of vesting for the remaining Loan Agreement warrants and allocated the probability of occurrence percentage to the fair values calculated.

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4. Short-term marketable securities

The following is a summary of short-term marketable securities as of June 30, 2022 and December 31, 2021:

	June 30, 2022				
	Amortized cost	Gross unrealized gains	Gross unrealized losses	Credit losses	Fair value
Money market funds	$ 151,791	$ —	$ —	$ —	$ 151,791
Corporate debt securities	3,001	—	(3)	—	2,998
	$ 154,792	$ —	$ (3)	$ —	$ 154,789
Cash equivalents					$ 151,791
Short-term marketable securities					2,998
					$ 154,789

	December 31, 2021				
	Amortized cost	Gross unrealized gains	Gross unrealized losses	Credit losses	Fair value
Money market funds	$ 116,261	$ —	$ —	$ —	$ 116,261
Corporate debt securities	37,802	—	(27)	—	37,775
	$ 154,063	$ —	$ (27)	$ —	$ 154,036
Cash equivalents					$ 116,261
Short-term marketable securities					37,775
					$ 154,036

As of June 30, 2022 and December 31, 2021, all of the Company's short-term marketable securities had contractual maturities of less than one year.

5. Accrued expenses and other current liabilities

The following is a summary of accrued expenses and other current liabilities as of June 30, 2022 and December 31, 2021:

	June 30, 2022	December 31, 2021
Accrued external research and development expenses	$ 16,847	$ 17,539
Accrued employee compensation and benefits	1,910	554
Accrued legal and professional fees	808	124
Short-term lease liability and other	255	205
	$ 19,820	$ 18,422

6. Loan Payable and Warrant Liability

On June 15, 2022, the Company entered into a Loan and Security Agreement ("Loan Agreement") with Hercules Capital, Inc. ("Hercules"), for an aggregate principal amount of $100,000 ("Term Loan"). Pursuant to the Loan Agreement, the Term Loan is available to the Company in four tranches, subject to certain terms and conditions.

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Under the terms of the Loan Agreement, the Company received $10,000 upon closing and an additional $10,000 is available to the Company at its sole discretion. The second tranche of the Term Loan, consisting of up to an additional $15,000, will become available to the Company subject to the Company's achievement of certain clinical development milestones. The third tranche of the Term Loan, consisting of up to an additional $20,000, will become available to the Company upon the achievement of certain clinical and financial milestones. The fourth tranche of the Term Loan, consisting of up to an additional $45,000, will become available to the Company at Hercules sole discretion.

The Term Loan will mature on January 1, 2027 (the “Maturity Date”). The Term Loan bears interest at a variable annual rate equal to the greater of (a) 7.65% and (b) the Prime Rate (as reported in the Wall Street Journal) plus 3.65% (the “Interest Rate”). The Company may make payments of interest only through July 1, 2024, which may be extended to July 1, 2025 upon the achievement of the third tranche milestones (the “interest-only period”). After the interest-only period, the principal balance and related interest will be required to be repaid in equal monthly installments and continuing until the Maturity Date.

The Loan Agreement contains customary closing fees, events of default, and representations, warranties and covenants, including a financial covenant requiring the Company to maintain a minimum cash balance in relation to the outstanding principal balance of the Term Loan. The Loan Agreement provides for a prepayment charge equal to 3% of the outstanding principal balance of the Term Loan if prepayment is made within the first twelve months after closing, 2% if within the second twelve months after closing and 1% thereafter. In addition, the Loan Agreement provides for an End of Term Charge that will be the greater of 5.85% of the outstanding principal balance or $1,170, which is recognized as a debt discount and is being accreted into the amortization of debt issuance costs and discount using the effective interest rate method over the term of the loan payable.

Upon closing, the Company issued warrants to Hercules to purchase shares of the Company’s common stock, par value $0.0001 per share ("common stock"). The amount of shares that may be purchased for the Warrants will not exceed 1.5% multiplied by the greater of Tranche I and the aggregate original amount of the term loan advances, divided by the exercise price of the Warrants.

The Company was in compliance with all covenants of the Loan Agreement as of June 30, 2022.

The Company determined in accordance with ASC 480-10 that the initial tranche one advance of $10,000, the additional Term Loan advances available under tranches one, two, three and four and the warrants issued upon closing shall be accounted for as freestanding financial instruments as they are legally detachable and separately exercisable. The Company also determined in accordance with ASC 815-10 that the additional Term Loan advances available under tranches one, two, three and four do not qualify as derivative instruments and that the value associated with these commitments is immaterial.

Upon closing, the Company issued to Hercules warrants to purchase 36,718 shares of Company’s common stock and recognized the initial warrants at their relative fair value of $227 in shareholders equity. In accordance with ASC 815-40, the additional remaining warrants to purchase shares of the Company’s common stock at the closing of the Loan Agreement were recognized at their fair value of $41 as warrant liabilities given the variable settlement amount of the warrant shares. The additional remaining warrants under the Loan Agreement are considered an outstanding instrument at close of the Loan Agreement. The total fair value of $268 associated with these equity and liability classified warrants, is recognized as a debt discount and is being accreted into the amortization of debt issuance costs and discount using the effective interest rate method over the term of the loan payable. The Company will reassess the fair value of the warrant liability at the end of each prospective reporting period. The change in fair value of the warrant liability from June 15, 2022 until June 30, 2022 was immaterial.

Future principal debt payments on the currently outstanding loan payable as of June 30, 2022 are as follows (in thousands):

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2022	$	—
2023		—
2024		1,764
2025		3,763
2026		4,096
2027		377
Total principal outstanding		10,000
End of term charge		1,170
Total principal outstanding and end of term charge		11,170
Unamortized discount and issuance costs		(1,804)
Loan Payable - noncurrent	$	9,366

The Company estimated the fair value of the Warrant using the Black-Scholes model based on the following key assumptions:

	Three months ended June 30, 2022
Expected term (in years)	7.00
Expected volatility	76.15 %
Weighted average risk-free interest rate	3.39 %
Expected dividend yield	0.00 %

7. Stockholder's equity (deficit)

Common stock

As of June 30, 2022 and December 31, 2021, the Company's certificate of incorporation, as amended and restated, authorized the Company to issue 150,000,000 shares of $0.0001 par value common stock. Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. The holders of common stock, voting exclusively and as a separate class, have the exclusive right to vote for the election of directors of the Company. Common stockholders are entitled to receive dividends, as may be declared by the board of directors. Through June 30, 2022, no cash dividends had been declared or paid.

On June 24, 2019, the Company completed its IPO at which time the Company issued 6,612,500 shares of common stock, including the exercise in full by the underwriters of their option to purchase up to 862,500 additional shares of common stock, at a public offering price of $16.00 per share. The Company received $98,394, net of underwriting discounts and commissions, but before deducting offering costs paid by the Company, which were $2,942. Upon the closing of the IPO, all outstanding shares of convertible preferred stock converted into 21,056,136 shares of common stock.

On July 10, 2020, the Company completed a follow-on public offering at which time the Company issued 6,012,390 shares of common stock, including the exercise in full by the underwriters of their option to purchase up to 784,224 additional shares of common stock, at a public offering price of $36.00 per share. The Company received $203,460 net of underwriting discounts and commissions, but before deducting offering costs paid by the Company, which were $906.

On May 18, 2021, the Company filed a Form S-3 Registration Statement and the accompanying prospectus activating an At-The-Market, or ATM, facility by entering into a sales agreement with J.P. Morgan Securities LLC, relating to shares of the Company's common stock offered. Pursuant to the terms of the sales agreement, the Company may offer and sell shares of common stock, having an aggregate price of up to $100,000, from time to time. The

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Company reserved 5,000,000 shares of common stock related to the ATM offering. During the three months ended June 30, 2022, the Company did not make any sales under the ATM facility.

On June 15, 2022, the Company entered into a securities purchase agreement for the sale of 2,525,252 shares of the Company's common stock to Pfizer Inc. at $9.90 per share in a registered direct offering conducted without an underwriter or placement agent and pursuant to the Company's effective shelf registration statement on Form S-3ASR and a related prospectus supplement filed with the SEC. The offering closed on June 17, 2022, for net proceeds of $24,647, after deducting offering costs paid by the Company which were $353.

As of June 30, 2022 and December 31, 2021, there were 37,570,326 and 34,900,727 shares of common stock issued and outstanding, respectively.

The following shares of common stock were reserved for issuance as follows:

	June 30, 2022	December 31, 2021
Options outstanding under the 2018 Stock Option and Grant Plan	1,889,683	2,011,891
Options outstanding under the 2019 Stock Option and Incentive Plan	3,881,675	3,209,203
Warrants to purchase common stock associated with Loan Agreement	36,718	—
Options available for future grant	2,612,856	1,889,299
Warrants available for future grant	146,880	—
Common stock available for ATM program	5,000,000	5,000,000
2019 Employee Stock Purchase Plan	1,199,297	872,429
	14,767,109	12,982,822

Undesignated preferred stock

The Company's fourth amended and restated certificate of incorporation authorizes the Company to issue up to 10,000,000 shares of undesignated preferred stock, par value $0.0001 per share. There were no undesignated preferred shares issued or outstanding as of June 30, 2022.

Warrants Associated with Loan Agreement

In connection with the entry into the Loan Agreement, the Company issued to Hercules warrants to purchase shares of the Company's common stock. The amount of shares that may be purchased for the Warrants will not exceed 1.5% multiplied by the greater of Tranche I and the aggregate original amount of the term loan advances, divided by the exercise price of the Warrants. Upon execution of the Loan Agreement, the Company issued 36,718 warrants to purchase shares of the Company's common stock and recorded the initial warrants at their relative fair value in shareholder's equity.

8. Stock-based awards

2018 Stock option and grant plan

The Company's 2018 Stock Option and Grant Plan (the "2018 Plan") provided for the Company to grant incentive stock options or nonqualified stock options, restricted stock awards and other stock-based awards to employees, directors and consultants of the Company. The 2018 Plan was administered by the board of directors or, at the discretion of the board of directors, by a committee of the board of directors. The exercise prices, vesting and other restrictions were determined at the discretion of the board of directors, or its committee if so delegated.

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The total number of shares of common stock that could have been issued under the 2018 Plan was 3,071,960 shares, of which 107,635 shares remained available for grant on June 18, 2019, the date that the Company's 2019 Stock Option and Incentive Plan (the "2019 Plan") became effective. Upon the effectiveness of the 2019 Plan, the 107,635 remaining shares available under the 2018 Plan were transferred and became available for issuance under the 2019 Plan. Shares of common stock underlying outstanding awards under the 2018 Plan that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by the Company prior to vesting, satisfied without the issuance of stock, expire or are otherwise terminated (other than by exercise) will be added to the shares of common stock available for issuance under the 2019 Plan.

2019 Stock option and incentive plan

The 2019 Plan was adopted and approved by the Company's board of directors in May 2019 and by the Company's stockholders in June 2019. The 2019 Plan became effective on June 18, 2019 and replaced the Company's 2018 Plan on that date. The 2019 Plan allows the board of directors or the compensation committee of the board of directors to make equity-based incentive awards to the Company's officers, employees, directors or other key persons (including consultants). The number of shares initially reserved for issuance under the 2019 Plan was 2,572,457, which included the 107,635 shares transferred from the 2018 Plan, and shall be cumulatively increased on each January 1 by 4% of the number of shares of the Company's common stock outstanding on the immediately preceding December 31 or such lesser number of shares determined by the Company's board of directors or compensation committee of the board of directors. The 2019 Plan was increased by 1,389,665 shares on January 1, 2021 and by 1,396,029 shares on January 1, 2022.

The 2019 Plan is administered by the board of directors or, at the discretion of the board of directors, by a committee of the board of directors. The exercise prices, vesting and other restrictions are determined at the discretion of the board of directors, or its committee if so delegated, except that the exercise price per share of stock options may not be less than 100% of the fair market value of the share of common stock on the date of grant and the term of stock option may not be greater than ten years. All incentive options granted to any person possessing more than 10% of the total combined voting power of all classes of shares may not have an exercise price of less than 110% of the fair market value of the common stock on the grant date. Stock options granted to employees, officers, members of the board of directors and consultants will typically vest over a four-year period.

Shares that are expired, terminated, surrendered or canceled under the 2019 Plan without having been fully exercised will be available for future awards.

2019 Employee stock purchase plan

The 2019 Employee Stock Purchase Plan (the "2019 ESPP") was adopted and approved by the Company's board of directors in May 2019 and by the Company's stockholders in June 2019. The 2019 ESPP became effective on June 18, 2019, at which time 273,869 shares were reserved for issuance. The 2019 ESPP provides that the number of shares reserved and available for issuance will automatically increase each January 1, beginning on January 1, 2020 and each January 1 through January 1, 2029, by the least of (i) 1% of the outstanding number of shares of the Company's common stock on the immediately preceding December 31, (ii) 410,803 shares or (iii) such number of shares as determined by the compensation committee. The 2019 ESPP was increased by 347,416 shares on January 1, 2021 and by 349,007 shares on January 1, 2022.

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Stock option valuation

The assumptions that the Company used to determine the grant-date fair value of stock options granted to employees, directors and consultants as follows, presented on a weighted average basis:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Expected term (in years)	5.75	5.66	5.77	5.86
Expected volatility	74.24 %	70.43 %	73.10 %	70.43 %
Weighted average risk-free interest rate	2.91 %	1.05 %	1.82 %	0.80 %
Expected dividend yield	0.00 %	0.00 %	0.00 %	0.00 %

Stock options

The following table summarizes the Company's stock option activity since December 31, 2021:

	Number of Options	Weighted-Average Exercise Price per Share	Weighted-Average remaining contractual term (years)	Aggregate Intrinsic Value (000's)
Balance outstanding, December 31, 2021	5,221,094	$ 15.49	8.20	36,168
Options granted	703,527	$ 18.10		
Options exercised	(122,208)	$ 1.21		
Options cancelled	(31,055)	$ 22.16		
Balance outstanding, June 30, 2022	5,771,358	$ 16.07	7.87	$ 10,986
Vested and expected to vest, June 30, 2022	5,189,977	$ 15.49	7.75	$ 10,986
Exercisable, June 30, 2022	2,719,542	$ 11.91	7.08	$ 9,145

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock.

The weighted average grant-date fair value per share of stock options granted during the three months ended June 30, 2022 and 2021 was $8.67 and $16.49, respectively. Additionally, the weighted average grant-date fair value per share of stock options granted during the six months ended June 30, 2022 and 2021 was $18.10 and $16.27, respectively.

Awards with performance-based vesting conditions granted under the 2019 Plan

In December 2021, the Company granted 610,546 stock options to management at an exercise price of $21.10, which vest upon the achievement on or before December 31, 2022 of three pre-determined milestones regarding progress related to the HARMONY study, progress related to the SYMMETRY study, and progress related to availability of drug product for use in Phase 3 clinical trials. One-third of the options vest upon achievement of each of the milestones. In January 2022, the Company granted an additional 248,376 stock options to Company employees with the same performance-based milestones and vesting terms at an exercise price of $21.70. During the three months ended June 30, 2022, the Company determined that it was probable that one of the milestones would be achieved and consequently recognized $911 of related stock compensation expense. In July 2022, the Company determined a second milestone was probable of being achieved and will begin recognizing stock compensation expense in the third quarter of 2022.

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Stock-based compensation

The following table summarizes the Company's stock-based compensation expense during the three and six months ended June 30, 2022 and 2021:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Classified within research and development expense	$ 1,474	$ 734	$ 2,585	$ 1,453
Classified within general and administrative expense	2,687	1,702	4,887	3,347
Total stock-based compensation expense	$ 4,161	$ 2,436	$ 7,472	$ 4,800

As of June 30, 2022, total unrecognized compensation cost related to unvested stock options was $36,635, including performance-based awards with unrecognized compensation costs of $10,021. These unvested stock options are expected to be recognized over a weighted average period of 1.78 years.

9. Amgen license agreement

In June 2018, the Company entered into a license agreement (the "Amgen Agreement") with Amgen, Inc. ("Amgen") pursuant to which the Company was granted an exclusive license to certain patents and intellectual property related to a long-acting FGF21 analog in order to commercially develop, manufacture, use and distribute FGF21 as a treatment for NASH and other serious metabolic diseases. The Amgen Agreement provides the Company with exclusive global rights to the licensed products and the right to grant sublicenses that cover EFX to third parties.

In exchange for these rights, the Company made an upfront payment of $5,000 and issued 2,653,333 shares of Series A Preferred Stock with a fair value of $1,353 to Amgen. Amgen was also entitled to maintain a 10% ownership interest of the outstanding shares of the Company's common stock, on a fully diluted and converted basis, through the second closing of the Company's Series A Preferred Stock financing. In November 2018, in connection with the second closing of the Company's Series A Preferred Stock financing, the Company issued 3,205,128 shares of Series A Preferred Stock to Amgen for a total value of $7,404, satisfying its anti-dilution obligation under the Amgen Agreement.

Under the Amgen Agreement, the Company made a milestone payment in the third quarter of 2019 of $2,500 in connection with dosing the first patient in the BALANCED study and is obligated to pay Amgen $7,500 in connection with dosing the first patient in a Phase 3 clinical trial, up to $30,000 in connection with marketing approvals, and aggregate milestone payments of up to $75,000 upon the achievement of specified commercial milestones for all products licensed under the Amgen Agreement.

Under the Amgen Agreement, the Company is obligated to pay Amgen tiered royalties ranging from a low to high single-digit percentages on annual net sales of the licensed products, beginning on the first commercial sale of such licensed products in each country and expiring on a country-by-country basis on the latest of (i) the expiration of the last valid patent claim covering such licensed products in such country, (ii) the loss of regulatory exclusivity in such country, and (iii) ten years after the first commercial sale of such licensed product in such country. The royalty payments are subject to reduction under specified conditions set forth in the Amgen Agreement.

The Company is solely responsible for all development, manufacturing, and commercial activities and costs of the licensed products, including clinical studies or other tests necessary to support the use of a licensed product. The Company is also responsible for costs related to the filing, prosecution and maintenance of the licensed patent rights.

The Amgen Agreement will remain in effect until the expiration of the royalty term in all countries for all licensed products. The Amgen Agreement may be terminated by either party with at least 90 days' notice in the event of material breach by the other party that remains uncured for 90 days, by either party for insolvency or bankruptcy of the

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other party and immediately by Amgen if the Company challenges the licensed patents. The Company may also terminate the Amgen Agreement with 90 days' written notice for discretionary reasons such as scientific, technical, regulatory or commercial issues, as defined in the Amgen Agreement.

During the three and six months ended June 30, 2022 and 2021, the Company did not record any research and development expense in connection with the Amgen Agreement.

10. Income taxes

During the three and six months ended June 30, 2022 and 2021, the Company did not record any income tax benefits for the net operating losses incurred or for the research and development tax credits generated in each period due to its uncertainty of realizing a benefit from those items. All of the Company's operating losses since inception have been generated in the United States.

On March 27, 2020, the Coronavirus Aid, Relief and Economic Security (CARES) Act, (the "Act") was signed into law. The Act includes provisions relating to refundable payroll tax credits, deferment of the employer portion of certain payroll taxes, net operating loss carryback periods, alternative minimum tax credit refunds, modifications to the net interest deduction limitations and technical corrections to tax depreciation methods for qualified improvement property. The Company analyzed the provisions of the Act and determined there was no significant impact to its income tax provision for the three and six months ended June 30, 2022.

On June 29, 2020, California Assembly Bill 85 ("AB85") was signed into law. AB85, which includes several tax measures, provides for a three-year suspension of the use of net operating losses for medium and large businesses and a three-year cap on the use of business incentive tax credits to offset no more than $5 million of tax per year. Generally, AB85 suspends the use of net operating losses for taxable years 2020, 2021 and 2022 for taxpayers with taxable income of $1 million or more. Since the Company is not expected to generate California source taxable income of more than $1 million during these periods, no material impact is anticipated at this time.

11. Net loss per share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Numerator:				
Net loss	$ (27,403)	$ (28,933)	$ (53,432)	$ (44,023)
Denominator:				
Weighted average common shares outstanding, basic and diluted	35,383,685	34,814,631	35,195,638	34,779,647
Net loss per share, basic and diluted	$ (0.77)	$ (0.83)	$ (1.52)	$ (1.27)

The Company excluded nil shares and 8,963 shares of restricted common stock, presented on a weighted average basis, from the calculations of basic net loss per share for the three months ended June 30, 2022 and 2021, respectively, because those shares had not vested. The Company excluded nil shares and 16,367 shares of restricted common stock, presented on a weighted average basis, from the calculations of basic net loss per share for the six months ended June 30, 2022 and 2021, respectively, because those shares had not vested.

The Company's potentially dilutive securities, which include stock options, warrants and unvested restricted common stock, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted average number of common shares outstanding used to calculate both

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basic and diluted net loss per share is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share for the periods indicated because including them would have had an anti-dilutive effect:

	Three and six months ended June 30,	
	2022	2021
Options to purchase common stock	5,771,358	3,962,372
Warrants to purchase common stock	36,718	—
Warrants available for future grant	146,880	—
Unvested restricted common stock	—	3,836
	5,954,956	3,966,208

12. Commitments and contingencies

COVID-19 Pandemic

In December 2019, a novel strain of coronavirus ("COVID-19") was reported to have surfaced in Wuhan, China and subsequently spread to other countries, including Europe and the United States, and was declared a pandemic by the World Health Organization. Despite progress with distribution and administration of vaccines, COVID-19 and its effects continue to evolve and countries including the United States, Europe and Asia continue to respond by implementing restrictions such as travel restrictions, social distancing requirements, stay-at-home orders and delayed commencement of non-COVID-19-related clinical trials. The Company's financial results for the three and six months ended June 30, 2022 and 2021 were not significantly impacted by COVID-19, however, the Company cannot at this time predict the specific extent, duration, or full impact that the ongoing COVID-19 pandemic will have on its financial condition, operations, and business plans for 2022, including the timing and enrollment of patients in its planned clinical trials and other expected milestones of its product candidate.

Operating lease

In February 2020, the Company entered into a seven-year agreement to occupy 6,647 square feet of office space in South San Francisco, California. The lease commenced on July 10, 2020 when the Company took occupancy of the leased space and the lease was determined to be operating classified. Under the agreement, the Company is required to make approximately $2,300 in total minimum payments during the term. The Company is also required to pay its proportionate share of building operating and tax costs after the first year under lease which are not included in the measurement of the lease and treated as variable lease cost and expensed when incurred.

As of June 30, 2022, maturities of the Company's operating lease liability was as follows:

2022 (remaining)	$	158
2023		321
2024		331
2025		341
2026		351
2027		208
Total future minimum lease payments		1,710
Less imputed interest		(293)
Present value of operating lease liabilities	$	1,417

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As of June 30, 2022, the total lease liability was $1,417, of which $1,199 was noncurrent and $218 was short-term and classified within "Accrued expenses and other current liabilities" on the condensed consolidated balance sheet.

For the three and six months ended June 30, 2022 and 2021, the components of operating lease cost were as follows:

		Three Months Ended June 30,		Six Months Ended June 30,	
		2022	2021	2022	2021
Lease cost:	Statement of Operations Classification:				
Operating lease cost	General and administrative expense	$ 81	$ 81	$ 162	$ 162
Short-term lease cost	General and administrative expense	—	—	29	—
Variable operating lease cost	General and administrative expense	31	—	43	—
Total operating lease cost		$ 112	$ 81	$ 234	$ 162
Other information:					
Cash paid for amounts included in the measurement of operating lease liability		$ 77	75	$ 154	$ 150
Weighted average remaining lease term		5.1	6.1	5.1	6.1
Weighted average discount rate		7.6%	7.6%	7.6%	7.6%

Research and manufacturing and other commitments

The Company has entered into agreements with contract research organizations and contract manufacturing organizations to provide services in connection with its nonclinical studies and clinical trials and to manufacture clinical development materials. As of June 30, 2022, the Company had non-cancelable purchase and other commitments under these agreements totaling $6,957.

Indemnification agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and its executive officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not currently aware of any indemnification claims and has not accrued any liabilities related to such obligations in its condensed consolidated financial statements as of June 30, 2022.

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Legal proceedings

The Company is not a party to any litigation and does not have contingency reserves established for any litigation liabilities. At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company expenses as incurred the costs related to such legal proceedings.

13. Subsequent event

The Company evaluated subsequent events through August 5, 2022, the date on which these financial statements were issued. Based on this evaluation, it was determined that no subsequent events occurred that require recognition or disclosure in its financial statements for the three months and six months ended June 30, 2022.

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

The following discussion should be read in conjunction with our financial statements and accompanying footnotes appearing elsewhere in this Quarterly Report on Form 10-Q and the audited financial statements and related notes contained in our Annual Report on Form 10-K for the year ended December 31, 2021. 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 and related financing, includes forward-looking statements that involve risks and uncertainties. See "Special Note Regarding Forward-Looking Statements." Because 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. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

Overview

We are a clinical-stage company dedicated to developing transformational treatments for patients with serious metabolic diseases marked by high unmet medical need, including non-alcoholic steatohepatitis, or NASH, a disease without any approved therapies. NASH is a severe form of nonalcoholic fatty liver disease, or NAFLD, characterized by inflammation and fibrosis in the liver that can progress to cirrhosis, liver failure, cancer and death. Our lead product candidate, efruxifermin, or EFX, is an analog of fibroblast growth factor 21, or FGF21, which is an endogenously expressed hormone that protects against cellular stress and regulates metabolism of lipids, carbohydrates and proteins throughout the body. EFX is currently being evaluated in two Phase 2b clinical trials in patients with biopsy-confirmed NASH: the HARMONY study in patients with pre-cirrhotic NASH (F2-F3 fibrosis) and the SYMMETRY study in patients with cirrhotic NASH (F4 fibrosis, compensated). The SYMMETRY study includes an expansion cohort, known as Cohort D, evaluating the safety and tolerability of EFX compared to placebo when added to an existing GLP-1 receptor agonist in patients with pre-cirrhotic NASH (F1-F3 fibrosis) and Type 2 Diabetes Mellitus, or T2D. Based on clinical data to date, which include substantial rates of fibrosis regression among patients with biopsy-confirmed NASH treated with EFX for only 16 weeks, we believe EFX has the potential, if approved, to be a best-in-class medicine for treating NASH.

All required visits for the Week 24 primary analysis in the ongoing Phase 2b HARMONY study in patients with pre-cirrhotic (F2-F3 fibrosis) NASH have been completed. Accordingly, Akero expects to report HARMONY results for the Week 24 primary endpoint (change from baseline in liver fibrosis with no worsening of steatohepatitis) and multiple secondary endpoints—including histology, noninvasive markers of liver injury, lipoproteins, measures of glycemic control, liver fat, body weight, and safety/tolerability, in September 2022. Based on enrollment to date, we expect to report results from the ongoing Phase 2b SYMMETRY main study in patients with cirrhosis due to NASH in the second half of 2023. In July 2022, the first patient was randomized into Cohort D, the expansion cohort of the Phase 2b SYMMETRY study.

The Phase 2b HARMONY and SYMMETRY studies build on the results of three prior randomized, double-blind, placebo-controlled clinical trials, in which a total of 162 adult patients with either NASH (n=79) or T2D, (n=83) were treated with EFX for up to 16 weeks. Our Phase 2a BALANCED study showed EFX's potential to reverse fibrosis and restore metabolic health while maintaining a favorable cardiovascular profile. Among 40 EFX patients with F1-F3 fibrosis who had end-of-treatment biopsies, 48% achieved at least a one-stage improvement in fibrosis without worsening of NASH and 48% achieved NASH resolution with no worsening of fibrosis. Improvements in metabolic health included significant relative reductions in liver fat (up to 71%), significant reductions in HbA1c (up to 0.9% in patients with both NASH and T2D), and significant reductions in triglycerides (up to 45%), a key attribute given that cardiovascular disease remains the number one cause of mortality in patients with NASH. Across EFX groups, the most frequent adverse events were grade 1 or 2 gastrointestinal events, which were mainly mild in nature.

Results among a subset of patients from the 16-week BALANCED main study who had F2 or F3 fibrosis at baseline, as well as results from an expansion cohort of patients with cirrhosis due to NASH (F4 fibrosis, compensated), support our confidence that we expect to continue to observe histological improvements in the ongoing, longer-duration HARMONY and SYMMETRY studies. For example, among BALANCED study patients who had F2/F3 fibrosis at baseline, 68% had at least a one-stage improvement in fibrosis, including 50% who had a two-stage fibrosis

improvement. We also observed that 33% of patients with cirrhosis due to NASH (F4 fibrosis, compensated) achieved a one-stage improvement in fibrosis without worsening of NASH after just 16 weeks.

The FDA and European Medicines Agency, or EMA, have respectively granted a Fast Track designation and a PRIority MEdicines, or PRIME, designation for EFX for the treatment of NASH. The Fast Track and PRIME programs are designed to enhance regulatory support for the development of promising investigational medicines where early clinical data suggest the potential to meet an unmet medical need. Benefits of these programs may include more frequent regulatory interactions, enhanced guidance on the overall development plan and regulatory strategy, and accelerated assessment of marketing authorization applications.

We believe the highly consistent results across three separate clinical trials in patients with T2D and/or NASH reflects the potential ability of EFX to uniquely reproduce the actions of native FGF21 and to potentially be a highly differentiated, best-in-class FGF21 analog and promising monotherapy for the treatment of NASH, if approved. NASH is a complex disease, and its treatment ideally would include intervening at all of the various stages of its pathogenesis. We believe EFX could potentially address all of the various stages of NASH pathogenesis in a single treatment: reversing fibrosis, resolving steatohepatitis, and helping to restore healthy metabolism to the whole body. We also believe EFX may be able to be used in combination with other therapies for potentially greater effect in certain subpopulations, particularly among the substantial proportion of patients with both NASH and T2D who are expected to be treated with GLP-1 therapeutics to manage their T2D.

We were incorporated in January 2017 and have devoted substantially all of our efforts to organizing and staffing our company, business planning, raising capital, in-licensing rights to EFX, research and development activities for EFX, building our intellectual property portfolio, exploring pipeline expansion opportunities, and providing general and administrative support for these operations. To date, we have principally raised capital through the issuance of convertible preferred stock and the initial public offering of our common stock in June 2019, an underwritten public offering of our common stock in July 2020 and through a term loan and a registered direct offering in June 2022. We have incurred significant operating losses since inception. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of EFX and any future product candidates. Our net losses were $27.4 million and $53.4 million for the three and six months ended June 30, 2022, respectively. Our net losses were $28.9 million and $44.0 million for the three and six months ended June 30, 2021, respectively. As of June 30, 2022, we had an accumulated deficit of $363.7 million.

We expect to continue to incur significant expenses for at least the next several years as we advance EFX through later-stage clinical development, develop additional product candidates and seek regulatory approval of any product candidates that complete clinical development. In addition, if we obtain marketing approval for any product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution.

We may also incur expenses in connection with the in-licensing or acquisition of additional product candidates. As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financings, or other capital sources, which may include collaborations with other companies or other strategic transactions. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, reduce or eliminate the development and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

As of June 30, 2022, we had cash, cash equivalents and short-term marketable securities of $180.7 million, which we believe will be sufficient, if combined with funds available to us from Hercules Capital, Inc., upon satisfaction of certain contingent milestones, to fund our current operating plan until the third quarter of 2024.

Impact of the COVID-19 Pandemic

As of August 2022, the ongoing COVID-19 pandemic continues to spread globally and evolve with emerging variants, such as Omicron, the BA.2 and BA.2.12.1, and more recently BA.4 and BA.5 subvariants and other SARS-CoV-2 viruses. Efforts to contain the spread of COVID-19 have intensified and are evolving. The effects of restrictions previously implemented by the United States, Europe and Asia led to delays in the commencement of non-COVID-19-related clinical trials. As a result, the COVID-19 pandemic has caused significant disruptions to the U.S., regional and global economies and has contributed to significant volatility and negative pressure in financial markets.

We have been carefully monitoring the COVID-19 pandemic and its potential impact on our business and have taken important steps to help ensure the safety of employees and their families and to reduce the spread of COVID-19. We have established, and maintained without interruption, a work-from-home policy for all employees. We have also maintained efficient communication with our manufacturing and supply partners as the COVID-19 situation has progressed. We have taken these precautionary steps while maintaining business continuity so that we can continue to progress our programs. Our financial results for the three and six months ended June 30, 2022 and for the years ended December 31, 2021 were not significantly impacted by COVID-19, and the COVID-19 pandemic did not materially impact data collection for the main portion of the BALANCED study, which was completed in 2021. In addition, our ongoing Phase 2b HARMONY trial, for which we completed enrollment in February 2022, and our ongoing SYMMETRY trial, for which enrollment remains open, have not been materially impacted by the COVID-19 pandemic.

Our manufacturing efforts to date have progressed without any adverse impact from COVID-19. Specifically, commercial-scale manufacture of GMP drug substance, or API, for our Phase 2b HARMONY and SYMMETRY studies was completed in April 2020. Manufacture of API for Phase 3 clinical trials was initiated on schedule in May 2021 and completed during the first quarter of 2022. Manufacture of GMP drug product for our Phase 2b HARMONY and SYMMETRY studies was completed in September 2020, with additional batches manufactured and completed in the third quarter of 2021. Scale-up of manufacturing of a new drug product formulation and delivery device for use in Phase 3 clinical trials, which is expected to be completed in 2022, has so far proceeded without any adverse impact from COVID-19.

Notwithstanding the foregoing, the future impact of the COVID-19 pandemic on our industry, the healthcare system and our current and future operations and financial condition will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the scope, severity and duration of the pandemic, the impact of new strains of the virus, the effectiveness and availability of vaccines and antiviral medications, the pace of these efforts, the actions taken to contain the pandemic or mitigate its impact, any additional preventative and protective actions that governments may direct, and the direct and indirect economic effects of the pandemic and containment measures, among others. See “Item 1A. Risk Factors” for a discussion of the potential adverse impact of COVID-19 on our business, results of operations and financial condition.

Components of our results of operations

Revenue

We have not generated any revenue since our inception and do not expect to generate any revenue from the sale of products in the near future, if at all. If our development efforts for EFX or additional product candidates that we may develop in the future are successful and result in marketing approval or if we enter into collaboration or license agreements with third parties, we may generate revenue in the future from a combination of product sales or payments from such collaboration or license agreements.

Operating expenses

Research and development expenses

Research and development expenses consist primarily of costs incurred in connection with the development of EFX, as well as unrelated discovery program expenses. We expense research and development costs as incurred. These expenses include:

- employee-related expenses, including salaries, related benefits and stock-based compensation expense for employees engaged in research and development functions;
- expenses incurred under agreements with CROs that are primarily engaged in the oversight and conduct of our clinical trials; CMOs that are primarily engaged to provide drug substance and product for our clinical trials, research and development programs, as well as investigative sites and consultants that conduct our clinical trials, nonclinical studies and other scientific development services;
- the cost of acquiring and manufacturing nonclinical and clinical trial materials, including manufacturing registration and validation batches;
- costs related to compliance with quality and regulatory requirements; and
- payments made under third-party licensing agreements.

Advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. Such amounts are recognized as an expense as the goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered or the services rendered.

Product candidates in later stages of clinical development, such as EFX, generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expenses will increase substantially in connection with our planned clinical development activities in the near term and in the future. At this time, we cannot accurately estimate or know the nature, timing and costs of the efforts that will be necessary to complete the clinical development of EFX and any future product candidates.

Our clinical development costs may vary significantly based on factors such as:

- per patient trial costs;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients enrolled in clinical trials;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;
- any setbacks or delays to the initiation or completion of preclinical or non-clinical studies, product development or clinical trials due to the COVID-19 pandemic;
- the cost and timing of manufacturing our product candidates, including on account of any disruption or delays to the supply of our product candidates due to the COVID-19 pandemic;
- the phase of development of our product candidates; and
- the efficacy and safety profile of our product candidates.

The successful development and commercialization of product candidates is highly uncertain. This is due to the numerous risks and uncertainties associated with product development and commercialization, including the following:

- the timing and progress of nonclinical and clinical development activities;
- the number and scope of nonclinical and clinical programs we decide to pursue;
- the ability to raise necessary additional funds;
- the progress of the development efforts of parties with whom we may enter into collaboration arrangements;
- our ability to maintain our current development program and to establish new ones;
- our ability to establish new licensing or collaboration arrangements;
- the successful initiation and completion of clinical trials with safety, tolerability and efficacy profiles that are satisfactory to the FDA or any comparable foreign regulatory authority;
- the receipt and related terms of regulatory approvals from applicable regulatory authorities;
- the availability of drug substance, drug product, and delivery devices utilized in the production of our product candidate;

- establishing and maintaining agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing, if our product candidate is approved;
- our ability to obtain and maintain patents, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- our ability to protect our rights in our intellectual property portfolio;
- the commercialization of our product candidate, if and when approved;
- obtaining and maintaining third-party insurance coverage and adequate reimbursement;
- the acceptance of our product candidate, if approved, by patients, the medical community and third-party payors;
- competition with other products;
- the impacts of a pandemic, epidemic or outbreak of an infectious disease, including COVID-19, on the supply of our product candidate and ability to successfully initiate and complete preclinical and non-clinical studies and clinical trials, to receive regulatory approval for our product candidate and to commercialize our product candidate, if approved; and
- a continued acceptable safety profile of our therapy following approval.

A change in the outcome of any of these variables with respect to the development of our product candidates could significantly change the costs and timing associated with the development of that product candidate. We may never succeed in obtaining regulatory approval for any of our product candidates.

General and administrative expenses

General and administrative expenses consist primarily of salaries and related costs for personnel in executive, finance, corporate and 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; marketing expenses and other operating costs.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support development of EFX and our continued research activities. We also anticipate that we will incur increased accounting, audit, legal, tax, regulatory, compliance, and director and officer insurance costs, as well as investor and public relations expenses associated with maintaining compliance with exchange listing and SEC requirements.

Interest expense

Interest expense consists primarily of interest expense on our term loan with Hercules.

Other income

Other income consists primarily of interest income earned on our cash, cash equivalents and short-term marketable securities.

Results of operations

Comparison of the three months ended June 30, 2022 and 2021

The following table summarizes our results of operations for the three months ended June 30, 2022 and 2021:

	Three Months Ended June 30,			
	2022	2021	$ Change	% Change
	(in thousands, except percentages)			
Operating expenses:				
Research and development	$ 21,363	$ 23,976	$ (2,613)	(11) %
General and administrative	6,231	4,990	1,241	25 %
Total operating expenses	27,594	28,966	(1,372)	(5) %
Loss from operations	(27,594)	(28,966)	1,372	(5) %
Interest expense	(53)	—	(53)	100 %
Other income	244	33	211	639 %
Net loss	$ (27,403)	$ (28,933)	$ 1,530	(5) %

Research and development expenses

The following table summarizes our research and development expenses incurred during the three months ended June 30, 2022 and 2021:

	Three Months Ended June 30,			
	2022	2021	$ Change	% Change
	(in thousands, except percentages)			
Research and development expenses:				
Direct EFX program expenses	$ 17,424	$ 21,605	$ (4,181)	(19) %
Personnel and other R&D related expenses	3,939	2,371	1,568	66 %
Total research and development expenses	$ 21,363	$ 23,976	$ (2,613)	(11) %

Research and development expenses were $21.4 million and $24.0 million for the three months ended June 30, 2022 and 2021, respectively, a decrease of $2.6 million. Direct costs for our EFX program decreased $4.2 million, attributed primarily to a $6.4 million decrease in third-party contract manufacturing expenses for EFX offset by a $2.2 million increase in CRO expenses related to our ongoing HARMONY and SYMMETRY clinical trials. Personnel and other research and development expenses increased $1.6 million, due to a $0.8 million increase in other R&D, wage and wage-related expenses resulting from increased staff and a $0.7 million increase in stock-based compensation. We expect that our research and development expenses will increase substantially in connection with our planned manufacturing and clinical development activities in the near term and in the future to support the ongoing programs.

General and administrative expenses

General and administrative expenses were $6.2 million and $5.0 million for the three months ended June 30, 2022 and 2021, respectively, an increase of $1.2 million which was due primarily to a $1.0 million increase in stock-based compensation and a $0.2 increase in other expenses and wage and wage-related expenses resulting from increased staff.

Interest expense

Interest expense the three months ended June 30, 2022 is comprised primarily of $0.1 million of interest expense related to the Hercules term loan that was entered into in June 2022.

Other income

Other income for the three months ended June 30, 2022 is comprised primarily of $0.2 million of interest income from our cash, cash equivalents and short-term marketable securities compared to less than $0.1 million for the three months ended June 30, 2021. This increase is related to increased investment returns on our cash, cash equivalents and short-term and marketable securities.

Comparison of the six months ended June 30, 2022 and 2021

The following table summarizes our results of operations for the six months ended June 30, 2022 and 2021:

	Six Months Ended June 30,			
	2022	2021	$ Change	% Change
	(in thousands, except percentages)			
Operating expenses:				
Research and development	$ 41,877	$ 34,578	$ 7,299	21 %
General and administrative	11,768	9,516	2,252	24 %
Total operating expenses	53,645	44,094	9,551	22 %
Loss from operations	(53,645)	(44,094)	(9,551)	22 %
Interest expense	(53)	—	(53)	100 %
Other income	266	71	195	275 %
Net loss	$ (53,432)	$ (44,023)	$ (9,409)	21 %

Research and development expenses

The following table summarizes our research and development expenses incurred during the six months ended June 30, 2022 and 2021:

	Six Months Ended June 30,			
	2022	2021	$ Change	% Change
	(in thousands, except percentages)			
Research and development expenses:				
Direct EFX program expenses	$ 34,579	$ 30,296	$ 4,283	14 %
Personnel and other R&D related expenses	7,298	4,282	3,016	70 %
Total research and development expenses	$ 41,877	$ 34,578	$ 7,299	21 %

Research and development expenses were $41.9 million and $34.6 million for the six months ended June 30, 2022 and 2021, respectively, an increase of $7.3 million. Direct costs for our EFX program increased $4.3 million, attributed primarily to a $7.8 million increase in CRO expenses related to our ongoing HARMONY and SYMMETRY clinical trials offset by a $3.1 million decrease in third-party contract manufacturing expenses for EFX. Personnel and other research and development expenses increased $3.0 million, due to a $1.9 million increase in other R&D, wage and wage-related expenses resulting from increased staff and a $1.1 million increase in stock-based compensation. We expect that our research and development expenses will increase substantially in connection with our planned manufacturing and clinical development activities in the near term and in the future to support the ongoing programs.

General and administrative expenses

General and administrative expenses were $11.8 million and $9.5 million for the six months ended June 30, 2022 and 2021, respectively, an increase of $2.3 million which was due primarily to a $1.6 million increase in stock-based compensation and a $0.3 increase in wage and wage-related expenses resulting from increased staff.

Interest expense

Interest expense the six months ended June 30, 2022 is comprised primarily of $0.1 million of interest expense related to the Hercules term loan that was entered into in June 2022.

Other income

Other income for the six months ended June 30, 2022 is comprised primarily of $0.3 million of interest income from our cash, cash equivalents and short-term marketable securities compared to $0.1 million for the six months ended June 30, 2021. This increase is related to increased investment returns on our cash, cash equivalents and short-term and marketable securities.

Liquidity and capital resources

From our inception through June 30, 2022, we have incurred significant operating losses. We have not yet commercialized any products and we do not expect to generate revenue from sales of products for several years, if at all. Through March 31, 2022, we had funded our operations primarily with proceeds from the sale of our redeemable convertible preferred stock, the initial public offering of our common stock in June 2019, and a follow-on public offering of our common stock in July 2020. In June 2022, we received $25.0 million from an equity investment from Pfizer, Inc. and $10.0 million from a Term Loan provided by Hercules. From our inception through June 30, 2022, these funding sources have provided gross proceeds totaling $447.7 million. As of June 30, 2022, we had cash, cash equivalents and short-term marketable securities of $180.7 million. We have invested our cash resources primarily in liquid money market accounts, commercial paper and corporate debt securities.

The following table summarizes our cash flows for the periods indicated:

	Six Months Ended June 30,	
	2022	2021
	(in thousands)	
Net cash used in operating activities	$ (42,385)	$ (38,380)
Net cash provided by investing activities	34,620	8,346
Net cash provided by financing activities	35,009	290
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 27,244	$ (29,744)

Cash flows from operating activities

Cash used in operating activities for the six months ended June 30, 2022 was $42.4 million, consisting of a net loss of $53.4 million and changes in our operating assets and liabilities of $3.3 million, offset by non-cash charges of $7.8 million, consisting primarily of stock-based compensation expense. The change in operating assets and liabilities was primarily due to the timing of prepayments and payments to our CMOs and CROs.

Cash used in operating activities for the six months ended June 30, 2021 was $38.4 million, consisting of a net loss of $44.0 million and changes in our operating assets and liabilities of $0.4 million, offset by non-cash charges of $5.2 million, consisting primarily of stock-based compensation expense. The change in operating assets and liabilities was primarily due to the timing of prepayments and payments to our CMOs and CROs.

Cash flows from investing activities

Cash provided by investing activities for the six months ended June 30, 2022 was $34.6 million from the maturities of short-term marketable securities.

Cash provided by investing activities for the six months ended June 30, 2021 was $8.3 million consisting of $40.0 million from the maturities of short-term marketable securities offset by $31.7 million in purchases of short-term marketable securities.

Cash flows from financing activities

Cash provided by financing activities for the six months ended June 30, 2022 was $35.0 million, including $25.0 million from an equity investment from Pfizer, Inc. through a registered direct common stock offering and $10.0 million from a Term Loan provided by Hercules.

Cash provided by financing activities for the six months ended June 30, 2021 was $0.3 million from the exercise of stock options and the issuance of employee stock purchase shares.

Description of Indebtedness

We have outstanding borrowings of $10.0 million under a loan and security agreement entered into in June 2022 with Hercules. We may borrow an additional $10.0 million at our sole discretion. Upon the occurrence of certain clinical development milestones, an additional $15.0 million may become available to us and upon the occurrence of certain clinical and financial milestones, an additional $20.0 million may become available to us. In addition, up to an additional $45.0 million will become available to the Company at Hercules' sole discretion. Borrowings under the loan are repayable in monthly interest-only payments until July 1, 2024, with the option to extend. The interest-only period will be followed by equal monthly payments of principal plus interest until the loan maturity date of January 1, 2027. Outstanding borrowings bear interest at the greater of (i) 7.65% and (ii) the prime rate as reported in the Wall Street Journal plus 3.65%.

Funding requirements

Our primary uses of capital are, and we expect will continue to be, research and development services, compensation and related expenses and general overhead costs. We expect to continue to incur significant expenses and operating losses for the foreseeable future. In addition, since the closing of our IPO, we have incurred and expect to continue to incur additional costs associated with operating as a public company. We anticipate that our expenses will increase significantly in connection with our ongoing activities. The timing and amount of our operating expenditures will depend largely on:

- the initiation, progress, timing, costs and results of nonclinical studies and clinical trials for EFX or any future product candidates we may develop;
- timing delays, if any, with respect to preclinical and clinical development of EFX or any future product candidates we may develop as a result of a pandemic, epidemic or outbreak of an infectious disease, including COVID-19;
- our ability to maintain our license to EFX from Amgen;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform more nonclinical studies or clinical trials than those that we currently expect or change their requirements on studies or trials that had previously been agreed to;
- the cost to establish, maintain, expand, enforce and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, defending and enforcing any patents or other intellectual property rights;
- the effect of competing technological and market developments;
- market acceptance of any approved product candidate, including product pricing, as well as product coverage and the adequacy of reimbursement by third-party payors;
- the cost of acquiring, licensing or investing in additional businesses, products, product candidates and technologies;
- the cost and timing of selecting, auditing and potentially validating a manufacturing site for commercial scale manufacturing;
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval and that we determine to commercialize; and
- our need to implement additional internal systems and infrastructure, including financial and reporting systems.

We expect that we will require additional funding to complete the clinical development of EFX, commercialize EFX, if we receive regulatory approval, and pursue in-licenses or acquisitions of other product candidates. If we receive regulatory approval for EFX or other product candidates, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution, depending on whether we choose to commercialize EFX ourselves.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, and marketing, distribution or licensing arrangements with third parties. To the extent that we raise additional capital through the sale of equity or convertible debt securities, ownership interest may be materially diluted, and the terms of such securities could include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specified actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, strategic alliances or marketing, distribution 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 or debt financings or other arrangements when needed, we may be required to delay, reduce or eliminate our product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Contractual obligations and other commitments

During the three and six months ended June 30, 2022, there have been no material changes outside the ordinary course of business to our contractual obligations and commitments from those disclosed in Management's Discussion and Analysis of Financial Condition and Results of Operations, set forth in Part II, Item 7, of our Fiscal 2021 Form 10-K, other than the Term Loan to Hercules Capital, Inc. discussed in Part I, Item 1, Footnote 6 to the Unaudited Condensed Consolidated Financial Statements of this Quarterly Report on Form 10-Q and to changes in our non-cancelable purchase arrangements.

Non-cancelable purchase and other arrangements decreased to $8.7 million as of June 30, 2022, compared to $9.3 million as of December 31, 2021. The decrease of $0.6 million was primarily attributable to $0.4 million decrease in the purchase and other obligations to support the growth and expansion of our clinical trials activities and a $0.2 million decrease in operating lease obligations for the office space in South San Francisco, California.

Critical accounting policies and estimates

This discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with United States generally accepted accounting principles. The preparation of our financial statements and related disclosures requires us to make estimates, assumptions and judgments that affect the reported amount of assets, liabilities, revenue, costs and expenses, and related disclosures. Our critical accounting policies are 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 year ended December 31, 2021 which was filed with the Securities and Exchange Commission on February 25, 2022. There were no material changes to our critical accounting policies through June 30, 2022 from those discussed in our Annual Report on Form 10-K for the year ended December 31, 2021.

Recent accounting pronouncements

See Note 2 to our unaudited condensed consolidated financial statements included in Part I, Item 1, “Notes to Unaudited Condensed Consolidated Financial Statements,” of this Quarterly Report on Form 10-Q for a description of recent accounting pronouncements applicable to our business.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

We are exposed to market risk related to changes in interest rates. We had cash, cash equivalents and marketable securities of $180.7 million as of June 30, 2022, which consisted primarily of money market funds, commercial paper, U.S. treasury securities and corporate debt securities, largely composed of investment grade, short to intermediate term fixed income securities.

The primary objective of our investment activities is to preserve capital to fund our operations. We also seek to maximize income from our investments without assuming significant risk. To achieve our objectives, we maintain a portfolio of investments in a variety of securities of high credit quality and short-term duration, according to our board-approved investment policy. Our investments are subject to interest rate risk and could fall in value if market interest rates increase.

Additionally, the Company has a variable interest rate term loan that is impacted by the increase in interest rates. A hypothetical 10% relative change in interest rates during any of the periods presented would not have a material impact on our condensed consolidated financial statements.

Foreign Currency Risk

The majority of our transactions occur in U.S. dollars. However, we do have certain transactions that are denominated in currencies other than the U.S. dollar, primarily the Euro and British Pound, and we therefore are subject to foreign exchange risk. The fluctuation in the value of the U.S. dollar against other currencies affects the reported amounts of expenses, assets and liabilities primarily associated with a limited number of manufacturing activities. The effect of a hypothetical 10% change in foreign currency exchange rates applicable to our business would not have had a material impact on our historical condensed consolidated financial statements for the three and six months ended June 30, 2022. As the impact of foreign currency exchange rates has not been material to our historical operating results, we have not entered into derivative or hedging transactions.

Inflation Risk

We do not believe that inflation has had a material effect on our business. However, if our costs, in particular costs related to manufacture and supply were to become subject to significant inflationary pressures, it may adversely impact our business, operating results and financial condition.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As required by Rule 13a-15(b) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), our management, under the supervision and with the participation of our principal executive officer (our Chief Executive Officer) and our principal financial officer (our Chief Financial Officer), have evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act as of June 30, 2022. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer (our Chief Executive Officer) and our principal financial officer (our Chief Financial Officer), as appropriate, to allow timely decisions regarding required disclosure. Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, as of the end of June 30, 2022, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

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

Inherent Limitations on Effectiveness of Controls

All control systems have inherent limitations including the realities that judgments in decision making can be faulty, and that breakdowns can occur because of a 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 management override of the controls. Because of such limitations, there is a risk that material misstatements will not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

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 June 30, 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 SEC. Investing in our common stock involves a high degree of risk. If any of the following risks and uncertainties actually occur, our business, prospects, financial condition, results of operations and cash flow could be materially and adversely affected. The risks 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, results of operations or cash flow.

Risks Related to the Clinical Development and Manufacturing of our Product Candidate

Risks Related to Clinical Development

Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control, including difficulties in identifying patients with NASH, significant competition for recruiting such patients in clinical trials, and restrictions on patients and investigators related to the ongoing COVID-19 pandemic.

Identifying and qualifying patients to participate in clinical trials is critical to our success. We may encounter delays in enrolling or be unable to retain a sufficient number of patients to complete the ongoing Phase 2b SYMMETRY study, or be unable to retain a sufficient number of patients to successfully complete the ongoing Phase 2b HARMONY study, and may encounter delays in enrolling or be unable to enroll or retain a sufficient number of patients in any of our future clinical trials. In particular, as a result of the inherent difficulties in diagnosing NASH and the significant competition for recruiting patients with NASH in clinical trials, there may be delays in enrolling the patients we need to complete clinical trials on a timely basis, or at all. This risk may be more significant for us than other companies conducting clinical trials for the treatment of patients with NASH because we are enrolling only patients with a biopsy-confirmed diagnosis of NASH in the SYMMETRY study and subsequent clinical trials. Further, if patients are unwilling to enroll in our clinical trials because of the impact of COVID-19 pandemic and restrictions on travel or healthcare institution policies or other impacts of the COVID-19 pandemic, the timeline for recruiting patients, conducting studies and obtaining regulatory approval of our product candidate may be delayed.

Factors that may generally affect patient enrollment include:

- the size and nature of the patient population;
- the number and location of clinical sites we enroll;
- the ability of our clinical sites to maintain adequate personnel;
- competition with other companies for clinical sites or patients;
- the eligibility and exclusion criteria for the trial;
- the design of the clinical trial;
- inability to obtain and maintain patient consents;
- risk that enrolled participants will drop out before completion; and
- competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating.

In addition, if any significant adverse events or other side effects are observed in any of our future clinical trials, it may make it more difficult for us to recruit patients to our clinical trials and patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of one or more product candidates altogether. Our inability to enroll a sufficient number of patients for our clinical trials could result in significant delays, which would increase our costs and have an adverse effect on our company.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than us.

The biotechnology industry is intensely competitive and subject to rapid and significant technological change. Our competitors include multinational pharmaceutical companies, specialized biotechnology companies and universities and other research institutions. We understand that a number of pharmaceutical companies, including AbbVie, Inc., AstraZeneca PLC/MedImmune LLC, Boehringer Ingelheim AG, Bristol-Myers Squibb Company, Inc., Eisai, Inc., Eli Lilly and Company, Johnson & Johnson, Merck & Co., Inc., Novartis Pharmaceuticals Corporation, Novo Nordisk A/S, Pfizer Inc., Roche Holding AG, Sanofi and Takeda Pharmaceutical Company Limited, as well as large and small biotechnology companies such as Albireo Pharma, Inc., Alnylam Pharmaceuticals, Inc., Altimmune, Inc., Amgen, Inc., Arrowhead Pharmaceuticals, Inc., Axcella Health, Inc., Boston Pharmaceuticals, Inc., Cirius Therapeutics, Inc., CohBar, Inc., CymaBay Therapeutics, Inc., 89bio, D&D Pharmatech, Inc., Enanta Pharmaceuticals, Inc., Galectin Therapeutics Inc., Galmed Pharmaceuticals Ltd., Gilead Sciences, Inc., Hanmi Pharmaceutical Company, Ltd., Intercept Pharmaceuticals, Inc., Inventiva Pharma SA, Ionics Pharmaceuticals, Inc., Madrigal Pharmaceuticals, Inc., MediciNova, Inc., North Sea Pharmaceuticals, Poxel SA, Sagimet Biosciences, Inc., Terns Pharmaceuticals, Inc. and Viking Therapeutics, Inc. are or may be pursuing the development or marketing of pharmaceuticals that target NASH. It is also probable that the number of companies seeking to develop products and therapies for the treatment of serious metabolic diseases, such as NASH, will increase. Many of our competitors have substantially greater financial, technical, human and other resources than we do and may be better equipped to develop, manufacture and market technologically superior products. In addition, many of these competitors have significantly greater experience than we have in undertaking nonclinical studies and human clinical trials of new pharmaceutical products and in obtaining regulatory approvals of human therapeutic products. Accordingly, our competitors may succeed in obtaining U.S. Food and Drug Administration, or FDA, approval for superior products. In addition, many competitors have greater name recognition and more extensive collaborative relationships.

Smaller and earlier-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

Our competitors may obtain regulatory approval of their products more rapidly than we do or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidate or any future product candidates. Our competitors may also develop drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than our products and these competitors may also be more successful than we are in manufacturing and marketing their products. If we are unable to compete effectively against these companies, then we may not be able to commercialize our product candidate or any future product candidates or achieve a competitive position in the market. This would adversely affect our ability to generate revenue. Our competitors also compete with us in recruiting and retaining qualified scientific, management and commercial personnel,

establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Failures or delays in the commencement or completion of, or ambiguous or negative results from our planned clinical trials of our product candidates could result in increased costs to us and could delay, prevent, or limit our ability to generate revenue and continue our business.

We do not know whether the HARMONY study or the SYMMETRY study, including the expansion cohort known as Cohort D, will be completed or any future clinical trials will begin or be completed on schedule, if at all, as the commencement and completion of clinical trials can be delayed or prevented for a number of reasons, including, among others:

- the FDA or comparable foreign regulatory authorities may not authorize us or our investigators to commence our planned clinical trials or any other clinical trials we may initiate, or may suspend our clinical trials, for example, through imposition of a clinical hold, and may request additional data to permit allowance of our investigational new drug, or IND;
- delays in filing or receiving allowance of additional IND applications that may be required;
- lack of adequate funding to continue our clinical trials and nonclinical studies;
- negative results from our ongoing nonclinical studies;
- delays in reaching or failing to reach agreement on acceptable terms with prospective clinical research organizations, or CROs, and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and study sites;
- inadequate quantity or quality of a product candidate or other materials necessary to conduct clinical trials, for example delays in the manufacturing of sufficient supply of finished drug product;
- difficulties obtaining ethics committee or Institutional Review Board, or IRB, approval to conduct a clinical study at a prospective site or sites;
- challenges in recruiting and enrolling subjects to participate in clinical trials, the proximity of subjects to study sites, eligibility criteria for the clinical study, the nature of the clinical study protocol, the availability of approved effective treatments for the relevant disease, and competition from other clinical study programs for similar indications;
- severe or unexpected drug-related side effects experienced by subjects in a clinical trial;
- we may decide, or regulatory authorities may require us, to conduct additional nonclinical or clinical trials or abandon product development programs;
- delays in validating, or inability to validate, any endpoints utilized in a clinical trial;
- the FDA or comparable foreign regulatory authorities may disagree with our clinical study design and our interpretation of data from clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials;
- difficulties retaining subjects who have enrolled in a clinical trial but may be prone to withdrawal due to rigors of the clinical trials, lack of efficacy, side effects, personal issues, or loss of interest; and
- the impact of COVID-19 on the initiation or completion of clinical trials or the reporting of results of our clinical trials and the supply of our product candidate.

Clinical trials may also be delayed or terminated as a result of ambiguous or negative interim results. In addition, a clinical study may be suspended or terminated by us, the FDA or comparable foreign regulatory authorities, the IRBs at the sites where the IRBs are overseeing a clinical study, a data and safety monitoring board, or DSMB, overseeing the clinical study at issue or other regulatory authorities due to a number of factors, including, among others:

- failure to conduct the clinical study in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical study operations or study sites by the FDA or other regulatory authorities that reveals deficiencies or violations that require us to undertake corrective action, including in response to the imposition of a clinical hold;
- unforeseen safety issues or safety signals, including any that could be identified in our ongoing nonclinical studies or clinical trials, adverse side effects or lack of effectiveness;
- changes in government regulations or administrative actions;
- problems with clinical supply materials; and

- lack of adequate funding to continue clinical trials.

Any inability to successfully complete nonclinical and clinical development could result in additional costs to us or impair our ability to generate revenue. In addition, if we make changes to a product candidate, such as developing the lyophilized formulation that we plan to employ, we may need to conduct additional nonclinical studies or clinical trials to bridge or demonstrate the comparability of our modified product candidate to earlier versions, which could delay our clinical development plan or marketing approval for our current product candidate and any future product candidates. Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

Clinical development is uncertain and our clinical trials for EFX and any future product candidates may experience delays, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all, which would have an adverse effect on our business.

We cannot be sure that we will be able to continue development of EFX or submit INDs or similar applications for any future product candidates, on the timelines we expect, if at all. To proceed with our development plans and ultimately commercialization, we may need to conduct and meet regulatory requirements for additional preclinical studies and clinical trials. We cannot be certain of the timely completion or outcomes of our preclinical testing and studies and cannot predict if the FDA or other regulatory authorities will accept our proposed clinical programs or if the outcomes of our preclinical studies and clinical trials will enable any future clinical trials to begin under a proposed protocol.

We rely and will continue to rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval of or commercialize any potential product candidates.

We depend and will continue to depend upon third parties, including independent investigators, to conduct our clinical trials under agreements with universities, medical institutions, CROs, strategic partners and others. We expect to have to negotiate budgets and contracts with CROs and trial sites, which may result in delays to our development timelines and increased costs.

We rely heavily on third parties over the course of our clinical trials, and, as a result, have limited control over the clinical investigators and limited visibility into their day-to-day activities, including with respect to their compliance with the approved clinical protocol. Nevertheless, our reliance on third parties does not relieve us of our regulatory responsibilities and we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards. We and these third parties are required to comply with good clinical practice, or GCP, requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to suspend or terminate these trials or perform additional nonclinical studies or clinical trials before approving our marketing applications. We cannot be certain that, upon inspection, regulatory authorities will determine that any of our clinical trials comply with the GCP requirements. In addition, our clinical trials must be conducted with products produced under current good manufacturing practice, or cGMP, requirements and may require a large number of patients. Our failure or any failure by these third parties to comply with these applicable regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

The third parties who conduct our clinical trials are not our employees and, except for remedies that may be available to us under our agreements with those third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing nonclinical and clinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other

product development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, such as due to the impacts of COVID-19, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates in a timely manner or at all. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

If any of our relationships with these third-party CROs or others terminate, we may not be able to enter into arrangements with alternative CROs or other third parties or to do so on commercially reasonable terms. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO begins work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines due to the impact of COVID-19 or for other reasons or if the quality or accuracy of the clinical data they obtain is compromised due to the failure (including by clinical sites or investigators) to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase substantially and our ability to generate revenues could be delayed significantly.

Risks Related to the Manufacturing of our Product Candidate

We are subject to many manufacturing risks, any of which could substantially increase our costs, delay clinical programs and limit supply of our products.

We have contracted with a third-party manufacturer, Boehringer Ingelheim Pharmaceuticals GmbH, to make EFX drug substance (active pharmaceutical ingredient, or API) to supply the HARMONY and SYMMETRY studies, and future clinical trials and for commercial sale, if approved. We have successfully manufactured API under GMP conditions, which has been released for clinical use. Similarly we have contracted with Vetter Pharma International GmbH, or Vetter, to manufacture EFX drug product, or DP, for clinical development and plan to enter into a future agreement for commercial supply at the appropriate time. Even though the GMP DP being used for our ongoing HARMONY study is similar to the DP that was used for the BALANCED study, which is stored as a frozen liquid until immediately before administration to trial subjects, the process of manufacturing our product is complex, highly regulated and subject to several risks, including:

- the manufacturing process is susceptible to product loss due to contamination by adventitious microorganisms, equipment failure, improper installation or operation of equipment, vendor or operator error and improper storage conditions. Even minor deviations from normal manufacturing processes could result in reduced production yields and quality as well as other supply disruptions. If microbial, viral, including COVID-19, or other contaminations are discovered in our products or in the manufacturing facilities in which our products are made, the manufacturing facilities may need to be closed for an extended period of time to investigate and eliminate the contamination;
- the manufacturing facilities in which our products are made could be adversely affected by equipment failures, labor and raw material shortages, pandemics, epidemics, or outbreaks of infectious disease, financial difficulties of our contract manufacturers, natural disasters, power failures, local political unrest and numerous other factors; and
- any adverse developments affecting manufacturing operations for our products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls or other interruptions in the supply of our products. We may also have to record inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more expensive manufacturing alternatives.

The manufacture of EFX requires significant expertise and capital investment, including the development of advanced manufacturing techniques and in-process controls. Manufacturers of these products sometimes encounter difficulties in production, especially during scale-up from the manufacturing process used for early clinical trials to a validated and qualified process needed for pivotal clinical trials and commercial launch. These problems include failure to meet target production costs and yields, failure to meet product release specifications, including stability of the product, quality assurance system failures, operator error and shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. We cannot assure you that any product quality issues relating to the manufacture of our product candidate or any future product candidates will not occur in the future.

We do not have, and we do not currently plan to acquire or build the facilities or internal capabilities to manufacture bulk drug substance, finished drug product or delivery device for use in clinical trials or commercialization. To a large extent, that makes us dependent on the goodwill of our contract manufacturing partners to quickly fix deviations that will inevitably occur during the manufacturing of our product. Any delay or interruption in the supply of clinical trial materials, including on account of the impact of the COVID-19 pandemic on our contract manufacturing partners, could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials altogether. Since the beginning of the COVID-19 pandemic, several vaccines for COVID-19 have received Emergency Use Authorization by the FDA and a number 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.

We have developed a new lyophilized, drug product formulation of EFX for use in Phase 3 clinical trials and, if EFX is approved, for commercialization. This formulation was developed under contract with a specialist formulation development company, Coriolis Pharma Research GmbH. We have contracted with Vetter Pharma International GmbH, or Vetter, to manufacture this formulation as a dual-chamber, pre-filled syringe combination product for use in Phase 3 clinical trials. Scale-up of manufacturing at Vetter and release of clinical batches is expected to be completed in 2022. There is no assurance that we will be successful in completing this development on a timely basis, including accounting for any impact of the COVID-19 pandemic, or at all, which could impede our development and commercialization strategy for EFX. Further, the FDA or other similar foreign regulatory bodies could require nonclinical studies or clinical trials to support introduction of any new formulation or its presentation as a drug-device combination product, which could increase our development costs and delay or prevent us from proceeding with future clinical trials or commercialization of EFX, if approved.

We contract with third parties for the manufacture of EFX and the delivery device utilized for EFX and expect to continue to do so for future clinical trials and for commercialization of EFX as well as for any future product candidates. This reliance on third parties increases the risk that we will not have sufficient quantities of EFX, or the delivery devices utilized for EFX, or any future product candidates or medicines or that such supply will not be available to us at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not have any manufacturing facilities. We currently rely, and expect to continue to rely, on third-party manufacturers for the manufacture of EFX, delivery devices utilized for EFX or any future product candidates for nonclinical and clinical testing and for commercial supply of any of these product candidates for which we obtain marketing approval. Reliance on third-party manufacturers may expose us to different risks than if we were to manufacture product candidates ourselves. To the extent any issues arise with our third-party manufacturers, we may be unable to establish any agreements with any other third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the possible breach of the manufacturing agreement by the third party;
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us; and

- reliance on the third party for regulatory compliance, quality assurance and safety and pharmacovigilance reporting.

Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside the United States. For our product candidates that are biologic-device combination products, third-party manufacturers may not be able to comply with cGMP regulatory requirements applicable to biologic-device combination products, including applicable provisions of the FDA's drug product cGMP regulations, device cGMP requirements embodied in the FDA's Quality System Regulation, or QSR, or similar regulatory requirements outside the United States. Our failure, or the failure of third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or medicines, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our medicines and harm our business and results of operations.

If any CMO with whom we contract fails to perform its obligations, we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different CMO, which we may not be able to do on reasonable terms, if at all. In either scenario, our clinical trials supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our product candidates may be unique or proprietary to the original CMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CMOs for any reason, we will be required to verify that the new CMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to or approved by the FDA or another regulatory authority. The delays associated with the verification of a new CMO could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a CMO may possess technology related to the manufacture of our product candidate that such CMO owns independently. This would increase our reliance on such CMO or require us to obtain a license from such CMO in order to have another CMO manufacture our product candidates. In addition, in the case of CMOs that supply our product candidate, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials. Any medicines that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

Any performance failure on the part of our existing or future manufacturers, such as delays in performance due to the ongoing COVID-19 pandemic, could delay clinical development or marketing approval. We are also unable to predict how the ongoing COVID-19 pandemic may affect our third-party manufacturers, including any potential disruptions to our global supply chain. We do not currently have arrangements in place for redundant supply of bulk drug substance or for the manufacture of our drug product-delivery device combination. If any one of our current contract manufacturers cannot perform as agreed, we may be required to replace that manufacturer. Although we believe that there potentially are alternative manufacturers who could manufacture our drug substance or drug product-delivery device combination or any future product candidates, we may incur added costs and delays in identifying and qualifying any such replacement.

Our current and anticipated future dependence upon others for the manufacture of EFX or any future product candidates or medicines may adversely affect our future profit margins and our ability to commercialize any medicines that receive marketing approval on a timely and competitive basis.

The manufacture of our product candidates is complex and we may encounter difficulties in production. If we or any of our third-party manufacturers encounter such difficulties, or fail to meet rigorously enforced regulatory standards, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

The processes involved in manufacturing our product candidates, including pre-filled, dual-chamber syringe presentations of our product candidates, are complex, expensive, highly regulated, and subject to multiple risks. Further, as product candidates are developed through nonclinical studies to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials.

In addition, the manufacturing process for any products that we may develop is subject to FDA and other comparable foreign regulatory authority approval processes and continuous oversight, and we will need to contract with manufacturers who can meet all applicable FDA and foreign regulatory authority requirements, including, for example, complying with cGMPs, applicable product tracking and tracing requirements and applicable QSRs, on an ongoing basis. If we or our third-party manufacturers are unable to reliably produce products to specifications acceptable to the FDA or other regulatory authorities, we may not obtain or maintain the approvals we need to commercialize such products. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or our contract manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging or comparability nonclinical or clinical trials or the repetition of one or more clinical trials, increase clinical study costs, delay approval of our product candidate, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations, and growth prospects.

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 the 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.

Risks Related to Our Business, Industry and Intellectual Property

Risks Related to Business Development

We are heavily dependent on the success of EFX, our only product candidate.

We currently have no products that are approved for commercial sale and may never be able to develop marketable products. We expect that a substantial portion of our efforts and expenditures over the next several years will be devoted to EFX, which is currently our only product candidate. Accordingly, our business currently depends heavily on the successful development, regulatory approval, and commercialization of EFX. We cannot be certain that EFX will receive regulatory approval or be successfully commercialized even if we receive regulatory approval. If we were required to discontinue development of EFX or if EFX does not receive regulatory approval or fails to achieve significant market acceptance, we would be delayed by many years in our ability to achieve profitability, if ever.

The research, testing, manufacturing, safety, efficacy, labeling, approval, sale, marketing, and distribution of EFX is, and will remain, subject to comprehensive regulation by the FDA and foreign regulatory authorities. Failure to obtain regulatory approval for EFX in the United States, Europe, Japan or other jurisdictions will prevent us from commercializing and marketing EFX in such jurisdictions.

Clinical development of EFX prior to the BALANCED study was conducted by Amgen, Inc., or Amgen, in patients with T2D. We did not conduct any of the development of EFX related to clinical trials in patients with T2D, and we have relied on Amgen to have conducted such research and development in accordance with the applicable protocol, legal, regulatory, and scientific standards, have accurately reported the results of all nonclinical studies and clinical trials conducted prior to our license of EFX, and have correctly collected and interpreted the data from these studies and trials. To the extent any of the foregoing has not occurred, our expected development time and development costs for EFX may be increased.

Even if we were to successfully obtain approval from the FDA and foreign regulatory authorities for EFX, any approval might contain significant limitations related to use, including limitations on the stage of disease EFX is approved to treat, as well as restrictions for specified age groups, warnings, precautions or contraindications. Furthermore, even if we obtain regulatory approval for EFX, we will still need to develop a commercial infrastructure or develop relationships with collaborators to commercialize, establish a commercially viable pricing structure and obtain coverage and adequate reimbursement from third-party payors, including government healthcare programs. If we, or any future collaborators, are unable to successfully commercialize EFX, we may not be able to generate sufficient revenue to continue our business.

We have expended and will continue to expend our limited resources to pursue a particular therapeutic candidate or indication, such as our focus on developing EFX for the treatment of NASH, and may fail to capitalize on therapeutic candidates or indications that may be more profitable or for which there is a greater likelihood of success.

We have focused our extensive research and development efforts on EFX for the treatment of NASH. Therefore, we have, and in the future may, forego or delay pursuit of opportunities with other therapeutic candidates or for other indications that later prove to have greater commercial potential. We are highly dependent on the success of the future clinical trials of EFX, the outcomes of which are uncertain. Because EFX is our first and only therapeutic candidate, if it encounters safety, efficacy, supply or manufacturing problems, developmental delays, regulatory or commercialization issues or other problems, the value of our platform could be greatly diminished and our development plans could be curtailed and our business would be significantly harmed.

Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and EFX for the treatment of NASH may not yield any commercially viable therapeutic candidates. If we do not accurately evaluate the commercial potential or target market for a particular therapeutic candidate or misread trends in the biopharmaceutical industry, in particular for serious metabolic diseases, we may relinquish valuable rights to that therapeutic candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such therapeutic candidate.

At any time and for any reason, we may determine that one or more of our discovery programs or pre- clinical or clinical therapeutic candidates or programs does not have sufficient potential to warrant the allocation of resources toward such program or therapeutic candidate. Accordingly, we may choose not to develop a potential therapeutic candidate or elect to suspend, deprioritize or terminate one or more of our discovery programs or preclinical or clinical therapeutic candidates or programs. Suspending, deprioritizing or terminating a program or therapeutic candidate in which we have invested significant resources, means we will have expended resources on a program that will not provide a full return on our investment and may have missed the opportunity to have allocated those resources to potentially more productive uses, including existing or future programs or therapeutic candidates.

If we fail to develop and successfully commercialize other product candidates, our business and future prospects may be harmed and our business will be more vulnerable to any problems that we encounter in developing and commercializing our product candidate.

Our product candidate and any future product candidates must undergo rigorous clinical trials and regulatory approvals, and success in nonclinical studies or earlier-stage clinical trials may not be indicative of results in future clinical trials. EFX and any future product candidates will be subject to rigorous and extensive clinical trials and extensive regulatory approval processes implemented by the FDA and similar regulatory bodies in other jurisdictions. The approval process is typically lengthy and expensive, and approval is never certain. As a company, our only experience with clinical trials is our recently completed BALANCED study and our ongoing HARMONY and SYMMETRY studies, and we have not yet completed the clinical trials required to obtain regulatory approval. We may not be able to conduct clinical trials at preferred sites, enlist clinical investigators, enroll sufficient numbers of participants or begin or successfully complete clinical trials in a timely fashion, such as on account of the COVID-19 pandemic, if at all. Our anticipated clinical trials may be insufficient to demonstrate that our potential products will be active, safe or effective. Additional clinical trials may be required if clinical trial results are negative or inconclusive, which will require us to incur additional costs and significant delays.

Success in nonclinical studies and earlier-stage clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the effectiveness and safety of a product candidate. In addition, the design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We may be unable to design and execute a clinical trial to support regulatory approval for a NASH therapy. In addition, there is a high failure rate for drugs and products proceeding through clinical trials. In fact, many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in nonclinical studies and earlier-stage clinical trials. Similarly, the outcome of nonclinical studies may not predict the success of clinical trials. Moreover, data obtained from nonclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may experience regulatory delays or rejections as a result of many factors, including due to changes in regulatory policy during the period of our product development. Additionally, we are developing a pre-filled, dual-chamber syringe presentation of EFX that is considered to be a biologic-device combination product by the FDA, and its BLA will require review and coordination by FDA's drug and device centers prior to approval. Any such delays could negatively impact our business, financial condition, results of operations and prospects. From time to time, we may publish interim ''top-line'' or preliminary data from our clinical trials. Preliminary or interim data from clinical trials that we may complete 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. Preliminary or interim data 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. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our business and financial prospects.

In addition, certain of our hypotheses regarding the potential clinical and therapeutic benefit of EFX compared to other candidates in development for NASH are based on cross-trial comparisons of results that were not derived from head-to-head preclinical studies or clinical trials. These observations, which do not reflect robust comparative analyses, may suggest misleading similarities or differences due to differences in study protocols, conditions and patient populations, and may not be reliable predictors of the relative efficacy or other benefits of EFX compared to other product candidates that are in development for the treatment of NASH.

We may develop EFX, and potentially future product candidates, in combination with other therapies, which exposes us to additional risks.

We may develop EFX and future product candidates in combination with one or more approved therapies. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or similar regulatory authorities outside of the United States could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. This could result in our own products being removed from the market or being less successful commercially.

We may also evaluate EFX or any other future product candidates in combination with one or more other therapies that have not yet been approved for marketing by the FDA or similar regulatory authorities outside of the United States. We will not be able to market and sell EFX or any product candidate we develop in combination with any such unapproved therapies that do not ultimately obtain marketing approval. If the FDA or similar regulatory authorities outside of the United States do not approve these other drugs or revoke their approval, or if safety, efficacy, manufacturing, or supply issues arise with the drugs we choose to evaluate in combination with EFX or any other product candidate we develop, we may be unable to obtain approval of or market EFX or any other product candidate we develop.

If we are not successful in discovering, developing, receiving regulatory approval for and commercializing EFX and any future product candidates, our ability to expand our business and achieve our strategic objectives would be impaired.

Although we plan to devote a majority of our resources to the continued nonclinical and clinical testing and potential approval of EFX for the treatment of patients with NASH, another key element of our strategy is to discover, develop and commercialize a portfolio of products. We are seeking to do so through the identification and potential development of additional pipeline programs, but our resources are limited, and those that we have are geared towards nonclinical and clinical testing and seeking regulatory approval of EFX for the treatment of patients with NASH. We may also explore strategic collaborations for the development or acquisition of new product candidates, but we may not be successful in entering into such relationships. EFX is our only product candidate in clinical stages of development. Research programs to identify product candidates require substantial technical, financial and human resources, regardless of whether any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including:

- the research methodology used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete;
- product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- a product candidate may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all;
- an approved product may not be accepted as safe and effective by trial participants, the medical community or third-party payors; and
- intellectual property or other proprietary rights of third parties for product candidates we develop may potentially block our entry into certain markets or make such entry economically impracticable.

Risks Related to our License and Third-Parties

We may be required to make significant payments under our license agreement for EFX.

We acquired worldwide, exclusive rights to EFX pursuant to our license agreement with Amgen, which we refer to as the Amgen Agreement. Under the Amgen Agreement, in consideration for the license, we made an upfront payment of $5.0 million to Amgen and also issued 2,653,333 shares of our Series A convertible preferred stock to Amgen at the time of the initial closing of our Series A Preferred Stock financing in June 2018, with a subsequent 3,205,128 shares of our Series A convertible preferred stock issued at the time of the second closing of the Series A Preferred Stock financing in November 2018. On July 2, 2019, we announced the dosing of the first patient in the BALANCED study of EFX, which resulted in a $2.5 million milestone obligation under the Amgen Agreement. As additional consideration for the license, we are required to pay Amgen $7.5 million in connection with dosing the first patient in a Phase 3 clinical trial, up to $30.0 million in connection with marketing approvals and aggregate milestone payments of up to $75.0 million upon the achievement of specified commercial milestones. Commencing on the first commercial sale of licensed products, we are obligated to pay tiered royalties of low to high single-digit percentages on annual net sales of the products covered by the license. If milestone or other non-royalty obligations become due, we may not have sufficient funds available to meet our obligations, which will materially adversely affect our business operations and financial condition.

If we breach our license agreement with Amgen related to EFX, we could lose the ability to continue the development and commercialization of EFX.

We are dependent on patents, know-how and proprietary technology in-licensed from Amgen. Our commercial success depends upon our ability to develop, manufacture, market and sell our product candidate or any future product candidates and use our and our licensor's proprietary technologies without infringing the proprietary rights of third parties. Amgen may have the right to terminate the license agreement in full in the event we materially breach or default in the performance of any of the obligations under the license agreement. A termination of the license agreement with Amgen could result in the loss of significant rights and could harm our ability to commercialize our product candidates.

Disputes may also arise between us and Amgen, as well as any future potential 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 on intellectual property 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 product candidate and what activities satisfy those diligence obligations; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

In addition, the Amgen Agreement under which we currently license intellectual property is complex, and certain provisions 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 increase what we believe to be our financial or other obligations under the Amgen Agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangement on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license, as we are for intellectual property that we own, which are described below. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could suffer.

We may seek to establish collaborations, and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

We may pursue collaborations in order to develop and commercialize EFX and any future product candidates. We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products and the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborators may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate.

Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we may not be able to further develop our product candidate or any future product candidates or bring them to market and generate product revenue.

Risks Related to Employee Matters and Growth

We must attract and retain highly skilled employees in order to succeed. If we are not able to retain our current senior management team and our scientific advisors or continue to attract and retain qualified scientific, technical and business personnel, our business will suffer.

To succeed, we must recruit, retain, manage and motivate qualified clinical, scientific, technical and management personnel and we face significant competition for experienced personnel. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our operating results. We are dependent on the members of our management team and our scientific advisors for our business success. We do not maintain “key person” insurance for any of our key personnel. An important element of our strategy is to take advantage of the research and development expertise of our current management and to utilize the expertise of our scientific advisors in the NASH field. We currently have employment agreements with all of our executive officers. Our employment agreements with our executive officers are terminable by them without notice and some provide for severance and change in control benefits. The loss of any one of our executive officers or key scientific consultants could result in a significant loss in the knowledge and experience that we, as an organization, possess and could cause significant delays, or outright failure, in the development and further commercialization of our product candidate or any future product candidates.

There is intense competition for qualified personnel, including management, in the technical fields in which we operate, and we may not be able to attract and retain qualified personnel necessary for the successful research, development and commercialization of EFX or any future product candidates. In particular, we have experienced a very competitive hiring environment in the San Francisco Bay Area, where we are headquartered. Many of the other pharmaceutical companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success with which we can discover and develop product candidates and our business will be limited.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We cannot ensure that our compliance controls, policies, and procedures will in every instance protect us from acts committed by our employees, agents, contractors, or collaborators that would violate the law or regulation, including, without limitation, healthcare, employment, foreign corrupt practices, environmental, competition, and patient privacy and other privacy laws and regulations. Such improper actions could subject us to civil or criminal investigations, and monetary and injunctive penalties, and could adversely impact our ability to conduct business, operating results, and reputation.

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to comply with the laws enforced by the FDA and other similar foreign regulatory bodies, fails to provide true, complete and accurate information to the FDA and other similar foreign

regulatory bodies, fails to comply with manufacturing standards we have established, fails to comply with healthcare fraud and abuse laws in the United States and similar foreign laws, or fails to report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under these laws will increase significantly, and our costs associated with compliance with these laws are also likely to increase. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. 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. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, and the curtailment or restructuring of our operations.

We may encounter difficulties in managing our growth, which could adversely affect our operations.

As of July 21, 2022, we had 37 full-time employees and one part-time employee. As we continue development and pursue the potential commercialization of EFX and other product candidates, as well as function as a public company, we will need to expand our financial, development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic collaborators, suppliers and other third parties. Our future financial performance and our ability to develop and commercialize our product candidate and to compete effectively will depend, in part, on our ability to manage any future growth effectively.

We may acquire additional technology and complementary businesses in the future. Acquisitions involve many risks, any of which could materially harm our business, including the diversion of management's attention from core business concerns, failure to effectively exploit acquired technologies, failure to successfully integrate the acquired business or realize expected synergies or the loss of key employees from either our business or the acquired businesses.

Risks Related to Protecting Our Intellectual Property

Our success depends upon our ability to obtain and maintain intellectual property protection for our products and technologies. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.

Our success will depend in significant part on our and our current or future licensors', licensees' or collaborators' ability to establish and maintain adequate protection of our intellectual property covering the product candidates we plan to develop, and the ability to develop these product candidates and commercialize the products resulting therefrom, without infringing the intellectual property rights of others. We strive to protect and enhance the proprietary technologies that we believe are important to our business, including seeking patents intended to cover our products and compositions, their methods of use, and any other inventions that are important to the development of our business. In addition to taking other steps to protect our intellectual property, we have applied for, and intend to continue to apply for, patents with claims covering our technologies, processes and product candidates when and where we deem it appropriate to do so. Our in-licensed patents and patent applications in both United States and certain foreign jurisdictions relate to EFX and related Fc-fusion polypeptides. There can be no assurance that the claims of our patents or any patent application that issues as a patent, will exclude others from making, using or selling our product candidate or any future product candidates or products that are substantially similar to our product candidate or any future product candidates. We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. In countries where we have not and do not seek patent protection, third

parties may be able to manufacture and sell our product candidate or any future product candidates without our permission, and we may not be able to stop them from doing so.

With respect to patent rights, we do not know whether any of the pending patent applications for our product candidate or any future product candidates will result in the issuance of patents that effectively protect our technologies, processes and product candidates, or if any of our issued patents or our current or future licensors', licensees' or collaborators' issued patents will effectively prevent others from commercializing competitive technologies, processes and products. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or in some cases not at all, until they are issued as a patent. Therefore, we cannot be certain that we or our current or future licensors, licensees or collaborators were the first to make or file on the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our current or future licensors, licensees or collaborators were the first to file for patent protection of such inventions. There is also no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which could be used by a third party to challenge the validity of our patents, should they issue, or prevent a patent from issuing from a pending patent application. Any of the foregoing could harm our competitive position, business, financial condition, results of operations, and prospects.

Any changes we make to our product candidate or any future product candidates, including formulations that may be required for commercialization, or that cause them to have what we view as more advantageous properties may not be covered by our existing patents and patent applications, and we may be required to file new applications and/or seek other forms of protection for any such altered product candidates. The patent landscape surrounding the technology underlying our product candidate or any future product candidates is crowded, and there can be no assurance that we would be able to secure patent protection that would adequately cover an alternative to our product candidate or any future product candidates.

The patent prosecution process is expensive and time-consuming, and we and our current or future licensors, licensees or collaborators may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our current or future licensors, licensees or collaborators will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection for them. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain or enforce the patents, covering technology that we license from or license to third parties and may be reliant on our current or future licensors, licensees or collaborators to perform these activities, which means that these patent applications may not be prosecuted, and these patents enforced, in a manner consistent with the best interests of our business. If our current or future licensors, licensees or collaborators fail to establish, maintain, protect or enforce such patents and other intellectual property rights, such rights may be reduced or eliminated. If our current or future licensors, licensees or collaborators are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised.

The patent positions of biotechnology and pharmaceutical companies, including our patent position, involve complex legal and factual questions, which in recent years have been the subject of much litigation, and, therefore, the issuance, scope, validity, enforceability, and commercial value of any patent claims that we have rights or may obtain cannot be predicted with certainty. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. As a result, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors', licensees' or collaborators' patent rights are highly uncertain. Our and our current or future licensors', licensees' or collaborators' pending and future patent applications may not result in patents being issued that protect our technology or product candidates, or products resulting therefrom, in whole or in part, or that effectively prevent others from commercializing competitive technologies and products. The patent examination process may require us or our current or future licensors, licensees or collaborators to narrow the scope of the claims of pending and future patent applications, which would limit the scope of patent protection that is obtained, if any. Our and our current or future licensors', licensees' or collaborators' patent applications cannot be enforced against third parties practicing the technology that is currently claimed in such applications unless and until a patent issues from such applications, and then only to the extent the claims that issue are broad enough to cover the technology being practiced by third parties.

Furthermore, 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 the resulting products are commercialized. As a result, our owned and in-licensed patents may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. We expect to seek extensions of patent terms for our issued patents, where available. This includes in the United States under the Hatch-Waxman Act, which permits a patent term extension of up to five years beyond the original expiration date of the patent as compensation for regulatory delays. However, such a patent term extension cannot lengthen the remaining term of a patent beyond a total of 14 years from the product's approval date. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent and within 60 days of product approval. During the period of patent term extension, the claims of a patent are not enforceable for their full scope but are instead limited to the scope of the approved product. In addition, the applicable authorities, including the FDA in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. In addition, we may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to the expiration of relevant patents or otherwise failing to satisfy applicable requirements. If this occurs, any period during which we have the right to exclusively market our product will be shorter than we would otherwise expect, and our competitors may obtain approval of and launch products earlier than might otherwise be the case.

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

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. A number of U.S. patents directed to various aspects of EFX will expire in 2029; we currently anticipate that a composition of matter patent will be eligible for patent term extension to 2034. Even if patents covering our product candidate or any future product candidate are obtained, once the patent life has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting our product candidate or any future product candidate might expire before or shortly after we or our partners commercialize those candidates. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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

The legal protection afforded to inventors and owners of intellectual property in countries outside of the United States may not be as protective or effective as that in the United States and we may, therefore, be unable to acquire and enforce intellectual property rights outside the United States to the same extent as in the United States. Whether filed in the United States or abroad, our patent applications may be challenged or may fail to result in issued patents.

In addition, our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing or commercializing competing products. Furthermore, others may independently develop or commercialize similar or alternative technologies or drugs, or design around our patents. Our patents may be challenged, invalidated, circumvented or narrowed, or fail to provide us with any competitive advantages. In many foreign countries, patent applications and/or issued patents, or parts thereof, must be translated into the native language. If our patent applications or issued patents are translated incorrectly, they may not adequately cover our technologies; in some countries, it may not be possible to rectify an incorrect translation, which may result in patent protection that does not adequately cover our technologies in those countries.

Filing, prosecuting, enforcing and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States are less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and certain state laws in the United States. Consequently, we and our licensor may not be able to prevent third parties from practicing our and our licensor's inventions in all countries outside the United States, or from selling or importing products made using our and our licensor's inventions in and into the United States or other jurisdictions. Competitors may use our and our licensor's 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 and our licensor have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidate or any future product candidates and our and our licensor's patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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

The requirements for patentability differ in certain countries, particularly developing countries. For example, China has a heightened requirement for patentability and, specifically, requires a detailed description of medical uses of a claimed drug. In addition, India, certain countries in Europe and certain developing countries, including Thailand, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensor may have limited remedies if patents are infringed or if we or our licensor are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. 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. Accordingly, our and our licensor's efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

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

Periodic maintenance and annuity fees on issued United States patents and most foreign patent applications and patents must be paid to the U.S. Patent and Trademark Office, or USPTO, and foreign patent agencies, respectively, in order to maintain such patents and patent applications. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application, examination and issuance processes. 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. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensor fail to maintain the patents and patent applications covering our product candidate or any future product candidates, our competitors might be able to enter the market with similar or identical products or technology, which would have a material adverse effect on our business, financial condition and results of operations.

We may be unable to obtain intellectual property rights or technology necessary to develop and commercialize EFX or any future product candidates.

Several third parties are actively researching and seeking and obtaining patent protection in the NASH field, and there are issued third-party patents and published third-party patent applications in these fields. However, we may not be aware of all third-party intellectual property rights potentially relating to our product candidate or any future product candidates and technologies.

Depending on what patent claims ultimately issue and how courts construe the issued patent claims, as well as depending on the ultimate formulation and method of use of our product candidate or any future product candidates, we

may need to obtain a license under such patents. There can be no assurance that such licenses will be available on commercially reasonable terms, or at all. If a third party does not offer us a necessary license or offers a license only on terms that are unattractive or unacceptable to us, we might be unable to develop and commercialize one or more of our product candidate or any future product candidates, which would have a material adverse effect on our business, financial condition and results of operations. Moreover, even if we obtain licenses to such intellectual property, but subsequently fail to meet our obligations under our license agreements, or such license agreements are terminated for any other reasons, we may lose our rights to in-licensed technologies.

The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment, or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our inability to protect our confidential information and trade secrets would harm our business and competitive position.

In addition to seeking patents for some of our technology and products, in our activities we also rely substantially on trade secrets, including unpatented know-how, technology and other proprietary materials and information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. However, these steps may be inadequate, we may fail to enter into agreements with all such parties or any of these parties may breach the agreements and disclose our proprietary information and there may be no adequate remedy available for such breach of an agreement. We cannot assure you that our proprietary information will not be disclosed or that we can meaningfully protect our trade secrets. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts both within and outside the United States may be less willing, or unwilling, to protect trade secrets. If a competitor lawfully obtained or independently developed any of our trade secrets, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position.

Risks Related to Intellectual Property Litigation

We may become involved in lawsuits or other proceedings to protect or enforce our intellectual property, which could be expensive, time-consuming and unsuccessful and have a material adverse effect on the success of our business.

Third parties may infringe our or our licensor's patents or misappropriate or otherwise violate our or our licensor's intellectual property rights. In the future, we or our licensor may initiate legal proceedings to enforce or defend our or our licensor's intellectual property rights, to protect our or our licensor's trade secrets or to determine the validity or scope of intellectual property rights we own or control. Also, third parties may initiate legal proceedings against us or our licensor to challenge the validity or scope of intellectual property rights we own, control or to which we have rights. For example, generic or biosimilar drug manufacturers or other competitors or third parties may challenge the scope, validity or enforceability of our or our licensor's patents, requiring us or our licensor to engage in complex, lengthy and costly litigation or other proceedings. These proceedings can be expensive and time-consuming and many of our or our licensor's adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. Moreover, the outcome following legal assertions of invalidity and unenforceability is unpredictable. Accordingly, despite our or our licensor's efforts, we or our licensor may not be able to prevent third parties from infringing upon or misappropriating intellectual property rights we own, control or have

rights to, particularly in countries where the laws may not protect those rights as fully as in the United States. Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, if we or our licensor initiated legal proceedings against a third party to enforce a patent covering a product candidate, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including 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, during prosecution. In an infringement or declaratory judgment proceeding, a court may decide that a patent owned by or licensed to us is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our or our licensor's patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our or our licensor's patents at risk of being invalidated, narrowed, held unenforceable or interpreted in such a manner that would not preclude third parties from entering the market with competing products.

Third-party pre-issuance submission of prior art to the USPTO, or opposition, derivation, revocation, reexamination, *inter partes* review or interference proceedings, or other pre-issuance or post-grant proceedings or other patent office proceedings or litigation in the United States or other jurisdictions provoked by third parties or brought by us or our licensor, may be necessary to determine the inventorship, priority, patentability or validity of inventions with respect to our or our licensor's patents or patent applications. An unfavorable outcome could leave our technology or product candidates without patent protection, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or could require us or our licensor to obtain license rights from the prevailing party in order to be able to manufacture or commercialize our product candidate or any future product candidates without infringing third-party patent rights. Our business could be harmed if the prevailing party does not offer us or our licensor a license on commercially reasonable terms, or at all. Even if we or our licensor obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensor. In addition, if the breadth or strength of protection provided by our or our licensor's patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or any future product candidates. Even if we successfully defend such litigation or proceeding, we may incur substantial costs and it may distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into collaborations.

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, many foreign jurisdictions have rules of discovery that are different than those in the United States and which may make defending or enforcing our or our licensor's patents extremely difficult. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock.

Third parties may initiate legal proceedings against us alleging that we infringe their intellectual property rights or we may initiate legal proceedings against third parties to challenge the validity or scope of intellectual property rights controlled by third parties, 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 any product candidates that we may develop and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. Third parties may initiate legal proceedings against us or our licensor alleging that we or our licensor infringe their intellectual property rights or we or our licensor may initiate legal proceedings against third parties to challenge the validity or scope of intellectual property rights controlled by third parties, including in oppositions, interferences, revocations, reexaminations, *inter partes* review or derivation proceedings before the USPTO or its counterparts in other jurisdictions. These proceedings can be expensive and time-consuming and many of our or our licensor's adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensor can.

An unfavorable outcome in any such proceeding could require us or our licensor to cease using the related technology or developing or commercializing our product candidate or any future product candidates, or to attempt to license rights to it from the prevailing party, which may not be available on commercially reasonable terms, or at all.

We could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidate or any future product candidates or force us to cease some of our business operations, which could materially harm our business.

We perform searches of patent and scientific databases in order to identify documents that may be of potential relevance to the freedom-to-operate and/or patentability of our product candidate or any future product candidates. In general, such searches are conducted based on keywords, sequences, inventors/authors and assignees/entities to capture U.S. and European patents and patent applications, PCT publications and scientific journal articles.

The patent landscape around our EFX product candidate is complex, and we may not be aware of all third-party intellectual property rights potentially relating to our product candidate or any future product candidates and technologies. Moreover, it is possible that we are or may become aware of patents or pending patent applications that we think do not relate to our product candidate or any future product candidates or that we believe are invalid or unenforceable, but that may nevertheless be interpreted to encompass our product candidate or any future product candidates and to be valid and enforceable. As to pending third-party applications, we cannot predict with any certainty which claims will issue, if any, or the scope of such issued claims. If any third-party intellectual property claims are asserted against us, even if we believe the claims are without merit, there is no assurance that a court would find in our favor, e.g., on questions of infringement, validity, enforceability or priority. A court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could materially and adversely affect our ability and the ability of our licensor to commercialize any product candidates we may develop, and any other product candidates or technologies covered by the asserted third-party patents. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. If any such third-party patents (including those that may issue from such applications) were successfully asserted against us or our licensor or other commercialization partners and we were unable to successfully challenge the validity or enforceability of any such asserted patents, then we or our licensor and other commercialization partners may be prevented from commercializing our product candidate or any future product candidates, or may be required to pay significant damages, including treble damages and attorneys' fees if we are found to willfully infringe the asserted patents, or obtain a license to such patents, which may not be available on commercially reasonable terms, or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects. Any of the foregoing would have a material adverse effect on our business, financial condition and operating results.

We may be subject to claims by third parties asserting that our employees or we have misappropriated a third party's intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees, including our senior management, were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. We may be subject to claims that we or these employees have used or disclosed confidential information or intellectual property, including trade secrets or other proprietary information, of any such employee's former employer, or that third parties have an interest in our patents as an inventor or co-inventor. Litigation may be necessary to defend against these claims. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain other damages. Such intellectual property rights could be

awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms, or at all. Even if we successfully prosecute or defend against such claims, litigation could result in substantial costs and distract management.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property 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 necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to any product candidates we may develop or utilize similar technology but that are not covered by the claims of the patents that we license or may own in the future;
- we, or our current or future collaborators, might not have been the first to make the inventions covered by the issued patents and pending patent applications that we license or may own in the future;
- we, or our current or future collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;
- it is possible that our pending patent applications or those that we may own in the future will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent application in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court or the USPTO.

If we or our licensing partner initiate legal proceedings against a third party to enforce a patent covering our product candidate or any 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 United States, 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. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. These types of mechanisms include *inter partes* review, post grant review, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). These types of proceedings could result in revocation or amendment to our patents such that they no longer cover our product candidates. The outcome for any particular patent following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel 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 product candidates. A loss of patent protection for our product candidates could have a material adverse impact on our ability to commercialize or license our technology and product candidates and, resultantly, on our business, financial condition, prospects and results of operations.

Likewise, patents directed to our proprietary technologies and our product candidates may expire before or soon after our first product achieves marketing approval in the United States or foreign jurisdictions. Upon the expiration of our current patents, we may lose the right to exclude others from practicing these inventions. The expiration of these patents could also have a similar material adverse effect on our business, financial condition, prospects and results of operations. A number of U.S. patents directed to various aspects of EFX will expire in 2029; we currently anticipate that a composition of matter patent will be eligible for patent term extension to 2034.

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

As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology industry involves technological and legal complexity, and obtaining and enforcing biotechnology patents is costly, time-consuming and inherently uncertain. 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, weakening the rights of patent owners in certain situations or ruling that certain subject matter is not eligible for patent protection. In addition to increasing uncertainty with regard to our and our licensor's ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the federal courts, the USPTO and equivalent bodies in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our and our licensor's ability to obtain new patents or to enforce existing patents and patents we and our licensor may obtain in the future.

Patent reform laws, such as the Leahy-Smith America Invents Act, or the Leahy-Smith Act, as well as changes in how patent laws are interpreted, could increase the uncertainties and costs surrounding the prosecution of our and our licensor's patent applications and the enforcement or defense of our or our licensor's issued patents, all of which could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Government Regulation

Risks Related to Obtaining Regulatory Approval

We have limited experience in conducting clinical trials and have never obtained approval for any product candidates, and may be unable to do so successfully.

As a company, other than the completed BALANCED study and our ongoing HARMONY and SYMMETRY studies, we have no experience in designing, conducting or completing clinical trials and have never progressed a product candidate through to regulatory approval. In part because of this lack of experience, our clinical trials may require more time and incur greater costs than we anticipate. We cannot be certain that the planned clinical trials will begin or conclude on time, if at all. Large-scale trials will require significant additional financial and management resources. Any performance failure on the part of such third parties could delay the clinical development of our product candidate or any future product candidates or delay or prevent us from obtaining regulatory approval or commercializing our current or any future product candidates, depriving us of potential product revenue and resulting in additional losses.

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable. Our inability to obtain regulatory approval for EFX or any future product candidate would substantially harm our business.

The time required to obtain approval from the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of nonclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of regulatory authorities. In addition, approval

policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's development and may vary among jurisdictions.

EFX or our future product candidates could fail to receive regulatory approval from the FDA or a comparable foreign regulatory authority for many reasons, including:

- disagreement with the design or implementation of our clinical trials;
- failure to demonstrate that a product candidate is safe and effective for its proposed indication;
- failure of clinical trials to meet the level of statistical significance required for approval;
- failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- disagreement with our interpretation of data from nonclinical studies or clinical trials;
- the insufficiency of data collected from clinical trials of EFX or any future product candidates to obtain regulatory approval;
- failure to obtain approval of the manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies; or
- changes in the approval policies or regulations that render our nonclinical and clinical data insufficient for approval.

The FDA or a comparable foreign regulatory authority may require more information, including additional nonclinical or clinical data to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program for other reasons. If we were to obtain approval, regulatory authorities may approve EFX or any future product candidates for fewer or more limited indications than we request, may require labeling or a Risk Evaluation Mitigation Strategy, or REMS, that includes significant use or distribution restrictions or safety warnings, precautions, or contraindications, 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.

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 approval timelines could be extended, including where a pre-approval inspection or an inspection of clinical sites is required and due to the 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.

Additional time may be required to obtain regulatory approval for our product candidates because they are combination products.

EFX is being developed, and future product candidates may be developed, as combination products that require coordination within the FDA and similar foreign regulatory agencies for review of their device and drug/biologic components. Medical products containing a combination of new drugs, biological products or medical devices may be regulated as "combination products" in the United States and Europe. A combination product generally is defined as a product comprised of components from two or more regulatory categories (e.g., drug/device, device/biologic, drug/biologic). Each component of a combination product is subject to the requirements established by the FDA for that type of component, whether a new drug, biologic or device. In order to facilitate premarket review of combination products, the FDA designates one of its centers to have primary jurisdiction for the pre-market review and regulation of the overall product based upon a determination by the FDA of the primary mode of action of the combination product. Where approval of the drug or biologic and device is sought under a single application, there could be delays in the approval process due to the increased complexity of the review process and the lack of a well-established review process and criteria. The EMA has a parallel review process in place for combination products, the potential effects of which in terms of approval and timing could independently affect our ability to market our combination products in Europe.

While we intend to seek designations for our product candidates with the FDA and comparable other regulatory authorities that are intended to confer benefits such as a faster development process or an accelerated regulatory pathway, there can be no assurance that we will successfully obtain such designations. In addition, even if one or more of our product candidates are granted such designations, we may not be able to realize the intended benefits of such designations.

The FDA and comparable other regulatory authorities offer certain designations for product candidates that are designed to encourage the research and development of product candidates that are intended to address conditions with significant unmet medical need. These designations may confer benefits such as additional interaction with regulatory authorities, a potentially accelerated regulatory pathway and priority review. Despite these designations, there can be no assurance that we will successfully obtain these or other designations for any of our other product candidates. In addition, while such designations could expedite the development or review process, they generally do not change the standards for approval. Even if we obtain such designations for one or more of our product candidates, there can be no assurance that we will realize their intended benefits.

For example, we may seek a Breakthrough Therapy designation for some of our product candidates. A breakthrough therapy is defined as a therapy that is intended, alone or in combination with one or more other therapies, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the therapy 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 therapies 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 control regimens. Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our 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 therapies 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 product candidates qualify as breakthrough therapies, the FDA may later decide that such product candidates no longer meet the conditions for qualification.

In addition, in October 2021, the FDA granted Fast Track designation for EFX for the treatment of NASH, and we may seek Fast Track Designation for some of our future product candidates. If a therapy is intended for the treatment of a serious or life-threatening condition and the therapy demonstrates the potential to address unmet medical needs for this condition, the therapy sponsor may apply for Fast Track Designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, there can be no assurance that the FDA would decide to grant it. Even if we do receive Fast Track Designation, as we have for EFX for the treatment of NASH, we may not experience a faster development process, review or approval compared to conventional FDA procedures, and receiving a Fast Track Designation does not provide assurance of ultimate FDA approval. In addition, the FDA may withdraw Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program.

Biologics designated as breakthrough therapies or granted Fast Track designation by the FDA may also be eligible for other expedited approval programs, including accelerated approval. A product candidate may be eligible for accelerated approval if it treats a serious or life-threatening condition, generally provides a meaningful advantage over available therapies, and demonstrates an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. As a condition of accelerated approval, the FDA may require that a sponsor of a product receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. These confirmatory trials must be completed with due diligence. Accelerated approval may also be withdrawn if, among other things, a confirmatory trial required to verify the predicted clinical benefit of the product fails to verify such benefit or if such trial is not conducted with due diligence. In addition, for products being considered for accelerated approval, the FDA generally requires, unless otherwise informed by the agency, that all advertising and promotional materials intended for dissemination or publication within 120 days of marketing approval be submitted to the agency for review during the pre-approval review period, which could adversely impact the timing of the commercial launch of the product. Thus, even if we seek to utilize the accelerated approval pathway, we may not be able to obtain accelerated approval and, even if we do, we may not experience a faster development, regulatory review or approval process for that product. In addition, receiving accelerated approval does not assure that the product’s accelerated approval will eventually be converted to a traditional approval.

We may seek priority review designation for one or more of our product candidates, but we might not receive such designation, and even if we do, such designation may not lead to a faster regulatory review or approval process.

If the FDA determines that a product candidate offers a treatment for a serious condition and, if approved, the product would provide a significant improvement in safety or effectiveness, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months. We may request priority review for our product candidates. The FDA has broad discretion with respect to whether or not to grant priority review status to a product candidate, so even if we believe a particular product candidate is eligible for such designation or status, the FDA may decide not to grant it. Moreover, a priority review designation does not result in expedited development and does not necessarily result in expedited regulatory review or approval process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Receiving priority review from the FDA does not guarantee approval within the six-month review cycle or at all.

Our failure to obtain regulatory approval in international jurisdictions would prevent us from marketing EFX or any future product candidates outside the United States.

We intend to market any approved products in the United States, the European Union, Japan and other foreign jurisdictions. Even if our products are approved for marketing in the United States, in order to market and sell our products in other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, we must secure product reimbursement approvals before regulatory authorities will approve the product for sale in that country. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries and regulatory approval in one country does not ensure approval in any other country. For example, even if EFX is approved in the United States, the EMA may require more information, including additional nonclinical or clinical data to support approval, which may delay or prevent approval and our commercialization plans in the European Union. Moreover, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others.

Also, regulatory approval for our product candidate or any future product candidates may be withdrawn if we fail to comply with regulatory requirements, if problems occur after the product candidate reaches the market or for other reasons. If we fail to comply with the regulatory requirements in international markets and fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidate or any future product candidates will be harmed and our business will be adversely affected. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions. Approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. If we fail to obtain approval of our product candidate or any future product candidates by regulatory authorities in another country, we will be unable to commercialize our product in that country, and the commercial prospects of that product candidate and our business prospects could decline.

Risks Related to Ongoing Regulatory Obligations

Even if we are able to obtain regulatory approvals for our product candidate or any future product candidates, if they exhibit harmful side effects after approval, our regulatory approvals could be revoked or otherwise negatively impacted, and we could be subject to costly and damaging product liability claims.

Clinical trials are conducted in representative samples of the potential patient population which may have significant variability. Even if we receive regulatory approval for EFX or any of our future product candidates, we will have tested them in only a small number of patients during our clinical trials. Clinical trials are by design based on a limited number of subjects and of limited duration for exposure to the product used to determine whether, on a

potentially statistically significant basis, the planned safety and efficacy of any product candidate can be achieved. As with the results of any statistical sampling, we cannot be sure that all side effects of our product candidates may be uncovered, and it may be the case that only with a significantly larger number of patients exposed to the product candidate for a longer duration, may a more complete safety profile be identified. Further, even larger clinical trials may not identify rare serious adverse effects or the duration of such studies may not be sufficient to identify when those events may occur. If our applications for marketing are approved and more patients begin to use our product, new risks and side effects associated with our products may be discovered. There have been other products that have been approved by the regulatory authorities but for which safety concerns have been uncovered following approval. Such safety concerns have led to labelling changes or withdrawal of products from the market, and any of our product candidates may be subject to similar risks. Additionally, we may be required to conduct additional nonclinical and clinical trials, require additional warnings on the label of our product candidate, reformulate our product or make changes, create a medication guide outlining the risks of such side effects for distribution to patients and obtain new approvals for our and our suppliers' manufacturing facilities for EFX and any future product candidates. We might have to withdraw or recall our products from the marketplace. We may also experience a significant drop in the potential sales of our product if and when regulatory approvals for such product are obtained, experience harm to our reputation in the marketplace or become subject to lawsuits, including class actions. Any of these results could decrease or prevent any sales of our approved product or substantially increase the costs and expenses of commercializing and marketing our product.

Even if our current product candidate or any future product candidates receive regulatory approval, they will remain subject to extensive regulatory scrutiny and may still face future development and regulatory difficulties.

Even if we obtained regulatory approval for a product candidate, regulatory authorities may still impose significant restrictions on our product candidates, including their indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval studies. For example, if EFX is approved by the FDA based on a surrogate endpoint pursuant to accelerated approval regulations (also referred to as Subpart E regulations), we will be required to conduct additional confirmatory clinical trials demonstrating the clinical benefit on the ultimate outcome of NASH. Further, even if we obtained regulatory approval for a product candidate, it would be subject to ongoing requirements by the FDA and comparable foreign regulatory authorities governing the manufacture, quality control, further development, labeling, packaging, storage, distribution, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-market information.

The FDA and comparable foreign regulatory authorities will continue to closely monitor the safety profile of any product even after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of our product candidate or any future product candidates, they may require labeling changes or establishment of a risk evaluation and mitigation strategy or similar strategy, impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance.

In addition, manufacturers of our products, if approved, and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP and applicable QSRs, regulations and standards. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we, EFX, or any future product candidates or the manufacturing facilities for EFX, the delivery device used for EFX, or any future product candidates fail to comply with applicable regulatory requirements, or undesirable side effects caused by such products are identified, a regulatory agency may:

- issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings about such product;
- mandate modifications to instructions for use;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require that we conduct post-marketing studies;

- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend marketing of, withdraw regulatory approval of or recall such product;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of products or require us to initiate a product recall.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product and generate revenue.

Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by the FDA, the Department of Justice, the Department of Health and Human Services' Office of Inspector General, state attorneys general, members of Congress and the public. Violations, including promotion of our products for unapproved (or off-label) uses, are subject to enforcement letters, inquiries and investigations, and civil and criminal sanctions by the government. Additionally, comparable foreign regulatory authorities will heavily scrutinize advertising and promotion of any product candidate that obtains approval outside of the United States.

In the United States, engaging in the impermissible promotion of our products for off-label uses can also subject us to false claims litigation under federal and state statutes, which can lead to civil and criminal penalties and fines and agreements that materially restrict the manner in which a company promotes or distributes drug products. These false claims statutes include the federal False Claims Act, which allows any individual to bring a lawsuit against a pharmaceutical company on behalf of the federal government alleging submission of false or fraudulent claims, or causing to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government prevails in the lawsuit, the individual will share in any fines or settlement funds. Since 2004, these federal False Claims Act lawsuits against pharmaceutical companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements regarding certain sales practices promoting off-label drug uses involving fines in excess of $1 billion. This growth in litigation has increased the risk that a pharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, agree to comply with burdensome reporting and compliance obligations and be excluded from Medicare, Medicaid and other federal and state healthcare programs. If we do not lawfully promote our approved products, we may become subject to such litigation and, if we do not successfully defend against such actions, those actions may have a material adverse effect on our business, financial condition and results of operations.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidate or any 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.

Risks Related to Healthcare Regulation

The advancement of healthcare reform may negatively impact our ability to profitably sell our product candidate or any future product candidates, if approved.

The United States 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 product candidate or any future product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any 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.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the Affordable Care Act or ACA, was enacted, which includes measures that have significantly changed the way health care is financed by both governmental and private insurers. Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an Executive Order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The Executive Order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how other healthcare reform measures of the Biden administrations or other efforts, if any, to challenge repeal or replace the ACA, will impact our business.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. In August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction, which triggered the legislation’s automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of, on average, 2% per fiscal year through 2030 unless Congress takes additional action. These reductions were extended through 2030. Pursuant to the Coronavirus Aid, Relief and Economic Security Act, or CARES Act, and subsequent legislation, the 2% Medicare sequester reductions were suspended from May 1, 2020 through March 31, 2022. Following the temporary suspension, a 1% payment reduction was in effect from April 1, 2022 through June 30, 2022, and the 2% payment reduction resumed on July 1, 2022. In January 2013, the American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. On April 13, 2017, CMS published a final rule that gives states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. In May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020. This final rule codified CMS’s policy change that was effective January 1, 2019. Additionally, on December 20, 2019, former President Trump signed into law the Further Consolidated Appropriations Act (H.R. 1865), which repealed the Cadillac tax, the health insurance provider tax, and the medical device excise tax. It is impossible to determine whether similar taxes could be instated in the future.

There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. At the federal level, the President Biden signed an Executive Order on July 9, 2021 affirming its policy (i) to support legislative reforms that would lower prescription drug prices, including by allowing Medicare to negotiate drug prices and by imposing inflation caps; and (ii) to support the enactment of a public health insurance option. Among other things, the Executive Order also directs HHS to submit a report to combat excessive pricing of prescription drugs, to enhance the domestic drug supply chain, to reduce the price that the Federal government pays for drugs, and to address price gouging in the industry; and directs the FDA to work with states to develop prescription drug importation plans pursuant to the Medicare Modernization Act of 2003 and FDA’s related implementing regulations. The FDA released such implementing regulations on September 24, 2020, which went into effect on November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020 CMS issued an Interim Final Rule implementing the Most Favored Nation, or MFN, Model under which Medicare Part B reimbursement rates will be calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. The MFN Model regulations mandate participation by identified Part B providers and would have applied to all U.S. states and territories for a seven-year period beginning January 1, 2021, and ending December 31, 2027. However, in response to a lawsuit filed by several industry groups, on December 28, the U.S. District Court for the Northern District of California issued a nationwide preliminary injunction enjoining government defendants from implementing the MFN Rule pending completion of notice-and-comment procedures under the Administrative Procedure Act. On January 13, 2021, in a separate lawsuit

brought by industry groups in the U.S. District of Maryland, the government defendants entered a joint motion to stay litigation on the condition that the government would not appeal the preliminary injunction granted in the U.S. District Court for the Northern District of California and that performance for any final regulation stemming from the MFN Interim Final Rule shall not commence earlier than 60 days after publication of that regulation in the Federal Register. Further, authorities in Canada have passed rules designed to safeguard the Canadian drug supply from shortages. If implemented, importation of drugs from Canada and the MFN Model may materially and adversely affect the price we receive for any of our product candidates. Additionally, on December 2, 2020, HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. On December 2, 2020, HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Pursuant to court order, the removal and addition of the aforementioned safe harbors were delayed and recent legislation imposed a moratorium on implementation of the rule until January 1, 2026. Further, implementation of this change and new safe harbors for point-of-sale reductions in price for prescription pharmaceutical products and pharmacy benefit manager service fees are currently under review by the Biden administration and may be amended or repealed. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that it will continue to seek new legislative measures to control drug costs. On July 9, 2021, President Biden issued an executive order directing the FDA to, among other things, continue to clarify and improve the approval framework for generic drugs and identify and address any efforts to impede generic drug competition.

Although a number of these, and other proposed measures may require additional authorization to become effective, and the Biden administration may reverse or otherwise change these measures, Congress has indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented 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.

We expect that the healthcare reform measures that have been adopted and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private third-party payors.

Further, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, or the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to request access to certain investigational new drug products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

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. In addition, regional healthcare 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 healthcare programs. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

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

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare providers, 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 research, and if approved, market, sell and distribute our products. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute prohibits persons from, among other things, knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, the referral of an individual for the furnishing or arranging for the furnishing, or the purchase, lease or order, or arranging for or recommending purchase, lease or order, of any good or service for which payment may be made under a federal healthcare program, such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;
- federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, which can be enforced through civil whistleblower or *qui tam* actions, prohibit individuals or entities from, among other things knowingly presenting, or causing to be presented, to the federal government or a government contractor, grantee, or other recipient of federal funds, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; knowingly making, using or causing to be made or used, a false statement or record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. Manufacturers can be held liable under the federal False Claims Act even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. The federal False Claims Act also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the federal False Claims Act and to share in any monetary recovery;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal liability for knowingly and willfully executing a scheme to defraud any healthcare benefit program, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense or knowingly and willfully making false statements relating to healthcare matters; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their implementing regulations, including the Final Omnibus Rule published in January 2013, imposes obligations on certain healthcare providers, health plans and healthcare clearinghouses, known as covered entities, as well as their business associates, which are individuals and entities that perform certain services involving the creation, maintenance, receipt, use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys’ fees and costs associated with pursuing federal civil actions. In addition, there may be additional federal, state and non-U.S. laws which govern the privacy and security of health and other personal information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts;

- federal price reporting laws, which require manufacturers to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on approved products;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

- the federal Open Payments program, created under Section 6002 of the Affordable Care Act and its implementing regulations, requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to "payments or other transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians (as defined above) and their immediate family members. As of January 1, 2022, these reporting obligations have now extended to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners; and
- analogous state, local, and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug prices; state and local laws that require the registration of pharmaceutical sales representatives; several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state and require the registration of pharmaceutical sales representatives. State and foreign laws, including for example the European Union General Data Protection Regulation, which became effective May 2018 also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and state and foreign laws that govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting 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 civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, that person or entity may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Failure to comply with health and data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business.

We and any potential collaborators may be subject to federal, state, and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act and California Consumer Privacy Act of 2018 ("CCPA")), that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators. The state of California, for example, recently adopted the CCPA, which went into effect beginning in

January 2020. The CCPA has been characterized as the first “GDPR-like” privacy statute to be enacted in the United States because it mirrors a number of the key provisions of the European Union General Data Protection Regulation, or GDPR (discussed below in the European Data Collection subsection). The CCPA establishes a new privacy framework for covered businesses by creating an expanded definition of personal information, establishing new data privacy rights for consumers in the State of California, imposing special rules on the collection of consumer data from minors, and creating a new and potentially severe statutory damages framework for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA, as amended by HITECH. While there is currently an exception for protected health information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA may impact some of our business activities. Depending on the facts and circumstances, we could be subject to civil, criminal, and administrative penalties if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

Further, a new California privacy law, the California Privacy Rights Act, or CPRA, was passed by California voters on November 3, 2020. The CPRA will create additional obligations with respect to processing and storing personal information that are scheduled to take effect on January 1, 2023 (with certain provisions having retroactive effect to January 1, 2022). Additionally, some observers have noted that the CCPA and CPRA could mark the beginning of a trend toward more stringent privacy legislation in the U.S., which could increase our potential liability and adversely affect our business. Already, in the United States, we have witnessed significant developments at the state level. For example, on March 2, 2021, Virginia enacted the Consumer Data Protection Act (the “CDPA”) and, on July 8, 2021, Colorado’s governor signed the Colorado Privacy Act (“CPA”), into law. The CDPA and the CPA will both become effective January 1, 2023. While the CDPA and CPA incorporate 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 regulated businesses. The new laws will, among other things, impact how regulated businesses collect and process personal sensitive data, conduct data protection assessments, transfer personal data to affiliates, and respond to consumer rights requests.

A number of other states have proposed new privacy laws, some of which are similar to the above discussed recently passed laws. 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. The existence of comprehensive privacy laws in different states in the country would make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance.

Compliance with U.S. and international data protection laws and regulations, including the EU GDPR and other EU data protection laws could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with these laws and regulations could result in government enforcement actions (which could include civil, criminal and administrative penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects, employees and other individuals about whom we or our potential collaborators obtain personal information, as well as the providers who share this information with us, may limit our ability to collect, use and disclose the information. Claims that we have violated individuals’ privacy rights, failed to comply with data protection laws, 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.

In the event we decide to conduct clinical trials or continue to enroll subjects in our ongoing or future clinical trials, we may be subject to additional privacy restrictions. The collection, use, storage, disclosure, transfer, or other processing of personal data regarding individuals in the EU, including personal health data, is subject to the EU General Data Protection Regulation, 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 United States, 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. 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 will be 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 U.K.'s exit from the EU on January 31, 2020, the GDPR ceased to apply in the U.K. at the end of the transition period on December 31, 2020. However, as of January 1, 2021, the U.K.'s European Union (Withdrawal) Act 2018 incorporated the U.K. GDPR into U.K. law. The U.K. GDPR and the U.K. Data Protection Act 2018 set out the U.K.'s data protection regime, which is independent from but aligned to the EU's data protection regime. Non-compliance with the U.K. 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 ("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.

To enable the transfer of personal data outside of the EEA or the UK, adequate safeguards must be implemented in compliance with European and UK data protection laws. On June 4, 2021, the EC issued new forms of standard contractual clauses for data transfers from controllers or processors in the EU/EEA (or otherwise subject to the GDPR) to controllers or processors established outside the EU/EEA (and not subject to the GDPR). The new standard contractual clauses replace the standard contractual clauses that were adopted previously under the EU Data Protection Directive. The UK is not subject to the EC's new standard contractual clauses but has published a draft version of a UK-specific transfer mechanism, which, once finalized, will enable transfers from the UK. We will be required to implement these new safeguards when conducting restricted data transfers under the EU and UK GDPR and doing so will require significant effort and cost.

Compliance with these and any other applicable privacy and data security laws and regulations is a rigorous and time-intensive process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. If we fail to comply with any such laws or regulations, we may face significant fines and penalties that could adversely affect our business, financial condition and results of operations.

Governments outside the United States tend to impose strict price controls, which may adversely affect our revenue, if any.

In some countries, particularly the countries of 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. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations. 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 drug candidate to other available procedures. If reimbursement of our drugs is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

Healthcare insurance coverage and reimbursement may be limited or unavailable for our product candidate, if approved, which could make it difficult for us to sell our product candidate or other therapies profitably.

The success of our product candidate, if approved, depends on the availability of coverage and adequate reimbursement from third-party payors including governmental healthcare programs, such as Medicare and Medicaid, commercial payors, and health maintenance organizations. We cannot be sure that coverage and reimbursement will be

available for, or accurately estimate the potential revenue from, our product candidates or assure that coverage and reimbursement will be available for any product that we may develop.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Coverage and adequate reimbursement from third-party payors are critical to new product acceptance.

Third-party payors decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

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

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a product from a third-party payor is a time consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about reimbursement for new medicines are typically made by CMS, an agency within HHS, as CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private third-party payors tend to follow Medicare coverage and reimbursement limitations to a substantial degree, but also have their own methods and approval process apart from Medicare determinations. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high.

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 United States.

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement.

In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price, or ASP, and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs.

Our activities in the United States subject us to various laws relating to foreign investment and the export of certain technologies, and our failure to comply with these laws or adequately monitor the compliance of our suppliers and others we do business with could subject us to substantial fines, penalties and even injunctions, the imposition of which on us could have a material adverse effect on the success of our business.

Because we have substantial operations in the United States, we are subject to U.S. laws that regulate foreign investments in U.S. businesses and access by foreign persons to technology developed and produced in the United States. These laws include Section 721 of the Defense Production Act of 1950, as amended by the Foreign Investment Risk Review Modernization Act of 2018, and the regulations at 31 C.F.R. Parts 800 and 801, as amended, administered by the Committee on Foreign Investment in the United States; and the Export Control Reform Act of 2018, which is being implemented in part through Commerce Department rulemakings to impose new export control restrictions on "emerging and foundational technologies" yet to be fully identified. Application of these laws, including as they are

implemented through regulations being developed, may negatively impact our business in various ways, including by restricting our access to capital and markets; limiting the collaborations we may pursue; regulating the export our products, services, and technology from the United States and abroad; increasing our costs and the time necessary to obtain required authorizations and to ensure compliance; and threatening monetary fines and other penalties if we do not.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, or FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties to sell our products sell our products outside the United States, to conduct clinical trials, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

Changes in funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new or existing product candidates from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Risks Related to Our Financial Condition and Need for Additional Capital

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

We have no products approved for commercial sale and have not generated any revenue to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred significant losses in each period since our inception in January 2017. For the six months ended June 30, 2022 and 2021, we reported net losses of $53.4 million and $44.0 million, respectively. For the years ended December 31, 2021 and 2020, we reported net losses of $100.8 million and $79.2 million, respectively. As of June 30, 2022, we had an accumulated deficit of $363.7 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidate. We anticipate that our expenses will increase substantially if, and as, we:

- conduct larger scale clinical trials for our product candidate, EFX, and any future product candidates;
- discover and develop new product candidates, and conduct nonclinical studies and clinical trials;
- incur setbacks or delays to the initiation or completion of preclinical and non-clinical studies, product development and/or clinical trials due to the COVID-19 pandemic;
- incur any disruption or delays to the supply of our product candidate due to the COVID-19 pandemic;
- manufacture, or have manufactured, clinical and commercial supplies of our product candidates;
- seek regulatory approvals for EFX or any future product candidates;
- commercialize EFX or any future product candidates, if approved;
- attempt to transition from a company with a development focus to a company capable of supporting commercial activities, including establishing sales, marketing and distribution infrastructure;
- hire additional clinical, scientific, and management personnel;
- add operational, financial, and management information systems and personnel;
- identify additional compounds or product candidates and acquire rights from third parties to those compounds or product candidates through licenses; and
- incur additional costs associated with operating as a public company.

Even if we succeed in commercializing EFX or any future product candidates, we may continue to incur substantial research and development and other expenditures to develop and market additional product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We currently have a limited operating history, have not generated any revenue to date, and may never become profitable.

We are a clinical-stage biotechnology company with a limited operating history. Our operations to date have been limited to organizing and staffing our company, acquiring, developing and securing our technology and product candidate, EFX, and conducting nonclinical studies and clinical trials of EFX. We have not yet demonstrated our ability to complete late-stage clinical trials, obtain regulatory approval, formulate and manufacture a commercial-scale product, or conduct sales and marketing activities necessary for successful product commercialization. Investment in biotechnology product development is highly speculative because it entails substantial upfront expenditures in clinical research organizations and contract manufacturing organizations and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. Consequently, any predictions you may make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

Though EFX is currently in Phase 2 clinical development, we do not expect to receive revenue from EFX for a number of years, if ever. To date, we have not generated any revenue and we will not be able to generate product revenue unless and until EFX, or any future product candidate, successfully completes clinical trials, receives regulatory approval, and is commercialized. We may seek to obtain revenue from collaboration or licensing agreements with third

parties. Our ability to generate future product revenue from EFX or any future product candidates also depends on a number of additional factors, including our, or our current and future contractors' and collaborators', ability to:

- successfully complete nonclinical studies and clinical trials for EFX and any future product candidates;
- seek and obtain marketing approvals for any product candidates that complete clinical development;
- establish and maintain supply and manufacturing relationships with third parties, and ensure adequate and legally compliant manufacturing of bulk drug substances and drug products to maintain that supply;
- launch and commercialize any product candidates for which we obtain marketing approval, and, if launched independently, successfully establish a sales, marketing and distribution infrastructure;
- demonstrate the necessary safety data post-approval to ensure continued regulatory approval;
- obtain coverage and adequate product reimbursement from third-party payors, including government payors;
- achieve market acceptance for any approved products;
- address any competing technological and market developments;
- maintain our rights under our existing license agreement with Amgen and any similar agreements we may enter into in the future;
- negotiate favorable terms in any collaboration, licensing or other arrangements into which we may enter in the future and performing our obligations in such collaborations;
- establish, maintain, protect and enforce our intellectual property rights; and
- attract, hire and retain qualified personnel.

In addition, because of the numerous risks and uncertainties associated with biotechnology product development, including that our product candidate may not advance through development or achieve the endpoints of applicable clinical trials, we are unable to predict the timing or amount of increased expenses, or if or when we will achieve or maintain profitability. In addition, our expenses could increase beyond expectations if we decide, or are required by the FDA or foreign regulatory authorities, to perform nonclinical studies or clinical trials in addition to those that we currently anticipate. Even if we complete the development and regulatory processes described above, we anticipate incurring significant costs associated with launching and commercializing any approved product.

If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company also could cause you to lose all or part of your investment.

We will require additional capital to finance our operations, which may not be available to us on acceptable terms, or at all. As a result, we may not complete the development and commercialization of our product candidate or develop any future product candidates.

As a research and development company, our operations have consumed substantial amounts of cash since inception. We expect our research and development expenses to increase substantially in connection with our ongoing activities, particularly as we advance EFX into later-stage clinical development.

As of June 30, 2022, we had $180.7 million of cash, cash equivalents and short-term marketable securities. We raised $95.5 million from our initial public offering in June 2019 and $202.6 million from our follow-on public offering in July 2020. We also raised gross proceeds of $25.0 million from Pfizer through a registered direct common stock offering and $10.0 million from Hercules under a term loan in June 2022. Any 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. The assumptions underlying any estimate may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Our future funding requirements, both short and long-term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of nonclinical studies and clinical trials for our product candidate or any future product candidates we may develop, including on account of any setbacks or delays due to the COVID-19 pandemic;

- the cost and timing of manufacturing our product candidate for use in clinical trials or, if approved by the FDA, for commercial use, including on account of any disruption or delays to the supply of our product candidate due to the COVID-19 pandemic;
- our ability to maintain our license to EFX from Amgen;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform more nonclinical studies or clinical trials than those that we currently expect or change their requirements on studies that had previously been agreed to;
- the cost to establish, maintain, expand, enforce and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, defending and enforcing any patents or other intellectual property rights;
- the effect of competing technological and market developments;
- market acceptance of any approved product candidates, including product pricing, as well as product coverage and the adequacy of reimbursement by third-party payors;
- the cost of acquiring, licensing or investing in additional businesses, products, product candidates and technologies;
- the cost and timing of selecting, auditing and potentially validating a manufacturing site for commercial scale manufacturing;
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval and that we determine to commercialize; and
- our need to implement additional internal systems and infrastructure, including financial and reporting systems.

We do not have any committed external source of funds or other support for our development efforts and we cannot be certain that additional funding will be available on acceptable terms, or at all. Until we can generate sufficient revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements, and other marketing or distribution arrangements. If we raise additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. Further, 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. If we raise additional capital through debt financing, we could be subject to fixed payment obligations and may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. We also could be required to seek collaborators for one or more of our current or any future product candidates at an earlier stage than otherwise would be desirable or relinquish our rights to product candidates or technologies that we otherwise would seek to develop or commercialize ourselves. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our products or product candidates or one or more of our other research and development initiatives. Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

Risks Related to Our Indebtedness

Our operating activities may be restricted as a result of covenants related to our Term Loan obligation, which we may be required to repay in an event of default, which could have a materially adverse effect on our business.

On June 15, 2022, we entered into the Loan Agreement with Hercules for an aggregate principal amount of up to $100.0 million. Until we have repaid such indebtedness, the Loan Agreement subjects us to various customary covenants, including requirements as to financial reporting and insurance, and restrictions on our ability to dispose of our business or property, to change our line of business, to liquidate or dissolve, to merge or consolidate with any other entity or to acquire all or substantially all the capital stock or property of another entity, to incur additional indebtedness,

to incur liens on our property, to pay any dividends or other distributions on capital stock other than dividends payable solely in capital stock, to redeem capital stock, to enter into licensing agreements, to engage in transactions with affiliates, or to encumber our intellectual property. Additionally, there is a financial covenant requiring us to maintain a minimum cash balance in relation to the outstanding principal balance of the Term Loan. Our business may be adversely affected by these restrictions on our ability to operate our business.

Additionally, we may be required to repay the outstanding indebtedness under the Term Loan if an event of default occurs under the Loan Agreement. Under the Loan Agreement, an event of default will occur if, among other things: we fail to make payments under the Loan Agreement; we breach any of our covenants under the Loan Agreement, subject to specified cure periods with respect to certain breaches; the Lender determines that a material adverse change has occurred; we or our assets become subject to certain legal proceedings, such as bankruptcy proceedings; we are unable to pay our debts as they become due; or we default on contracts with third parties which would permit the holder of indebtedness to accelerate the maturity of such indebtedness or that could have a material adverse change on us. As a result of the occurrence of an event of default, Hercules could accelerate all of the amounts due. In the event of an acceleration of amounts due under the Term Loan, we may not have enough available cash or be able to raise additional funds through equity or debt financings to repay such indebtedness at the time any such event of default occurs. In this case, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant to others rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Our business, financial condition and results of operations could be materially adversely affected as a result of any of these events.

Our level of indebtedness and debt service obligations could adversely affect our financial condition and may make it more difficult for us to fund our operations.

The Term Loan with Hercules provides up to $100.0 million of debt financing and has interest-only payments through July 1, 2024, which may be extended based on achievement of certain milestones. Thereafter, we are obligated to make payments that will include equal installments of principal and interest through the maturity date of January 1, 2027.

This indebtedness may create additional financing risk for us, particularly if our business or prevailing financial market conditions are not conducive to paying off or refinancing our outstanding debt obligations at maturity. This indebtedness could also have important negative consequences, including the fact that:

- we will need to repay our indebtedness by making payments of interest and principal, which will reduce the amount of money available to finance our operations, our research and development efforts and other general corporate activities; and
- our failure to comply with the restrictive covenants in the Term Loan could result in an event of default that, if not cured or waived, would accelerate our obligation to repay this indebtedness, and Hercules could seek to enforce our security interest in the assets securing such indebtedness.

Risks Related to Commercialization and Market Acceptance

Risks Related to Commercialization

Even if we commercialize EFX or any future product candidates, if approved, these products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which could harm our business.

The regulations that govern marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. 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 or product licensing 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 in a particular country, but then be subject to price regulations that delay or limit our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenue we generate from the sale of

the product in that particular country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidate or any future product candidates obtain marketing approval.

Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third-party payors such as government health administration authorities, private health insurers and other organizations. Third-party payors determine which medications they will cover and establish reimbursement levels. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval, if any. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize any product candidate for which marketing approval is obtained, if any.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a 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 only be temporary. 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 United States. Our inability to promptly obtain coverage and profitable reimbursement rates third-party payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidate or any future product candidates in human clinical trials and will face an even greater risk if we commercialize any resulting products. Product liability claims may be brought against us by subjects enrolled in our clinical trials, patients, their family members, healthcare providers or others using, administering or selling our products. If we cannot successfully defend ourselves against claims that our product candidate or any future product candidates or products that we may develop caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- termination of clinical trial sites or entire trial programs;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial subjects or patients;
- loss of revenue;
- diversion of management and scientific resources from our business operations;
- the inability to commercialize any products that we may develop; and
- a decline in our stock price.

Our clinical trial liability insurance coverage may not adequately cover all liabilities that we may incur. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Our inability to obtain product liability insurance at an acceptable cost or to otherwise protect against potential product liability claims could prevent or delay the commercialization of any products or product candidates that

we develop. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain marketing approval for our product candidate or any future product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. Large judgments have been awarded in lawsuits based on drugs that had unanticipated side effects. If we are sued for any injury caused by our products, product candidates or processes, our liability could exceed our product liability insurance coverage and our total assets. Claims against us, regardless of their merit or potential outcome, may also generate negative publicity or hurt our ability to obtain physician adoption of our product or expand our business.

Risks Related to Market Acceptance

If, in the future, we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market any product candidates we may develop, we may not be successful in commercializing those product candidates if and when they are approved.

We do not currently have an infrastructure for the sales, marketing, and distribution of pharmaceutical products. In order to market our product candidates, if approved by the FDA or any other regulatory body, we must build our sales, marketing, managerial, and other non-technical capabilities, or make arrangements with third parties to perform these services. There are risks involved with both establishing our own commercial capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force or reimbursement specialists is expensive and time-consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing and other commercialization 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 commercialization personnel.

If we enter into arrangements with third parties to perform sales, marketing, commercial support, and distribution services, our product revenue or the profitability of product revenue may be lower than if we were to market and sell any products we may develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to commercialize our product candidates or may be unable to do so on terms that are favorable to us. We may 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 products effectively and they could expose our company to regulatory enforcement and legal risk in the execution of their sales and commercialization activities. If we do not establish commercialization capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates if approved.

If we are unable to establish adequate sales, marketing, and distribution capabilities, whether independently or with third parties, or if we are unable to do so on commercially reasonable terms, our business, results of operations, financial condition, and prospects will be materially adversely affected.

Our product candidate or any future product candidates may not achieve adequate market acceptance among physicians, patients, third-party payors and others in the medical community necessary for commercial success.

Even if our product candidate or any future product candidates receive regulatory approval, they may not gain adequate market acceptance among physicians, patients, third-party payors, pharmaceutical companies and others in the medical community. Demonstrating the safety and efficacy of our product candidate or any future product candidates and obtaining regulatory approvals will not guarantee future revenue. Our commercial success also depends on coverage and adequate reimbursement of our product candidate or any future product candidates by third-party payors, including government payors and private insurers, which may be difficult or time-consuming to obtain, may be limited in scope and may not be obtained in all jurisdictions in which we may seek to market our products. Third-party payors closely examine medical products to determine whether they should be covered by reimbursement and, if so, the level of reimbursement that will apply. We cannot be certain that third-party payors will sufficiently reimburse sales of our product or enable us to sell our product at a profitable price. Similar concerns could also limit the reimbursement amounts that health insurers or government agencies in other countries are prepared to pay for our products. In many regions, including Europe, Japan and Canada, where we may market our products, the pricing of prescription drugs is controlled by the government or regulatory agencies. Regulatory agencies in these countries could determine that the

pricing for our products should be based on prices of other commercially available drugs for the same disease, rather than allowing us to market our products at a premium as new drugs. The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including:

- the efficacy and safety profile of the product candidate as demonstrated in clinical trials;
- the timing of market introduction of the product candidate as well as competitive products;
- any impact to market health as a result of COVID-19;
- the clinical indications for which the product candidate is approved;
- acceptance of the product candidate as a safe and effective treatment by clinics and patients;
- the potential and perceived advantages of the product candidate over alternative treatments, including any similar generic treatments;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement and pricing by third-party payors;
- the relative convenience and ease of administration;
- the frequency and severity of adverse events;
- the effectiveness of sales and marketing efforts; and
- unfavorable publicity relating to our product candidate or any future product candidates.

Sales of medical products also depend on the willingness of physicians to prescribe the treatment, which is likely to be based on a determination by these physicians that the products are safe, therapeutically effective and cost effective. In addition, the inclusion or exclusion of products from treatment guidelines established by various physician groups and the viewpoints of influential physicians can affect the willingness of other physicians to prescribe the treatment. We cannot predict whether physicians, physicians' organizations, hospitals, other healthcare providers, government agencies or private insurers will determine that our product is safe, therapeutically effective and cost effective as compared with competing treatments. If any product candidate is approved but does not achieve an adequate level of acceptance by such parties, we may not generate or derive sufficient revenue from that product candidate and may not become or remain profitable.

Risks Related to Our Operations

We incur significant costs and expend significant time and effort, as a result of operating as a public company, and our management is required to devote substantial time to compliance initiatives and corporate governance practices.

We incur significant legal, accounting and other expenses, and expend significant time and effort by management and other personnel, to comply with the rules applicable to us as a public company. We are subject to the reporting requirements of Nasdaq and of the Securities Exchange Act of 1934, as amended, which require, among other things, that we file with the Securities and Exchange Commission (SEC), annual, quarterly, and current reports with respect to our business and financial condition and that we establish and maintain effective disclosure controls, procedures and corporate governance practices. We must also comply with the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), and specifically Section 404 of the Sarbanes-Oxley Act. Section 404 generally requires our management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting and requires us to include an opinion from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting. We incur significant legal, accounting and other expenses, and expend significant time and effort by management and other personnel, to comply with the rules applicable to us as a public company and we will continue to need to do so. Despite these efforts, there is no guarantee that we will be able to conclude that our internal controls over financial reporting are effective.

Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act (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. 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 carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of our internal control over financial reporting for the purpose of providing the reports required by Section 404. Based on our assessment and using the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, criteria, our management, Chief Executive Officer and Chief Financial Officer, have concluded that, as of June 30, 2022, our internal control over financial reporting was effective. As required under Section 404 of Sarbanes-Oxley, we are required to have our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting. During the course of our or their subsequent review and testing, however, material weaknesses or significant deficiencies may be identified, and we may be unable to remediate them before we must provide the required reports. If material weaknesses or significant deficiencies in our internal control over financial reporting are identified in the future, we may not detect or remediate errors on a timely basis and our consolidated financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from NASDAQ or other adverse consequences that would materially harm our business.

We expect the rules and regulations applicable to public companies 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.

If we fail to comply with these rules, including maintaining proper and effective systems of internal controls over financial reporting, the accuracy and timeliness of our financial reporting may be adversely affected, and we could be subject to sanctions or other penalties that would harm our business.

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate consolidated 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 consolidated financial statements in accordance with generally accepted accounting principles. If we identify any material weakness or significant deficiency, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, investors may lose confidence in our financial reporting, and our stock price may decline as a result. We also could become subject to investigations by Nasdaq, the Securities and Exchange Commission, or SEC, or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets. In addition, investors' perceptions that our internal controls are inadequate or that we are unable to produce accurate consolidated financial statements on a timely basis may harm our stock price and make it more difficult for us to effectively market and sell our products to new and existing customers.

Our business and operations would suffer in the event of computer system failures, cyber-attacks or deficiencies in our or related parties' cyber security.

Given our limited operating history, we are still in the process of implementing our internal security measures. Our internal computer systems and those of current and future third parties on which we rely may fail and are vulnerable to damage from computer viruses and unauthorized access. Geopolitical instability, including Russia's invasion of Ukraine may increase cyber-attacks. Our information technology and other internal infrastructure systems, including corporate firewalls, servers, leased lines and connection to the Internet, face the risk of systemic failure that could disrupt our operations. While we have not, to our knowledge, experienced any such material system failure 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 development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in:

- delays in our regulatory approval efforts;
- remediation costs, such as liability for stolen assets or information, repairs of system damage, and incentives to business partners in an effort to maintain relationships after an attack;
- increased cybersecurity protection costs, which may include the costs of making organizational changes, deploying additional personnel and protection technologies, training employees, and engaging third party experts and consultants;
- increased insurance premiums;
- reputational damage that adversely affects customer or investor confidence;
- damage to the company's competitiveness, stock price, and long-term shareholder value; and
- significantly increase our costs to recover or reproduce the data.

Likewise, we currently rely, and expect to continue to rely, on third parties for the manufacture of our product candidate or any future product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of our product candidate or any future product candidates could be hindered or delayed.

We use and generate materials that may expose us to material liability.

Our research programs involve the use of hazardous materials and chemicals, which are currently only handled by third parties. We are subject to foreign, federal, state and local environmental and health and safety laws and regulations governing, among other matters, the use, manufacture, handling, storage and disposal of hazardous materials and waste products. We may incur significant costs to comply with these current or future environmental and health and safety laws and regulations. In addition, we cannot completely eliminate the risk of contamination or injury from hazardous materials and may incur material liability as a result of such contamination or injury. In the event of an accident, an injured party may seek to hold us liable for any damages that result. Any liability could exceed the limits or fall outside the coverage of our workers' compensation, property and business interruption insurance and we may not be able to maintain insurance on acceptable terms, if at all. We currently carry no insurance specifically covering environmental claims.

Risks Related to the COVID-19 Pandemic

Our business could be adversely affected by the effects of health epidemics, and has been impacted by the ongoing COVID-19 pandemic, in regions where we, or third parties on which we rely, have significant manufacturing, analytical laboratory and transportation facilities, concentrations of clinical trial sites or other business operations. The COVID-19 pandemic and any current or new variants of the virus could materially affect our operations, including at our headquarters in the San Francisco Bay Area, and at our clinical trial sites, as well as the business or operations of our manufacturers, CROs or other third parties with whom we conduct business.

Our business could be adversely affected by health epidemics in regions where we have concentrations of clinical trial sites or other business operations, and could cause significant disruption in the operations of third-party manufacturers and CROs upon whom we rely. For example, in December 2019, a novel strain of coronavirus, SARS-CoV-2, causing a disease referred to as COVID-19, was reported to have surfaced in Wuhan, China. Since then, COVID-19 has continued to spread globally, including in all 50 states within the United States. In March 2020, the World Health Organization declared COVID-19 a pandemic, and the U.S. government-imposed travel restrictions on travel between the United States, Europe and certain other countries. We have instituted work-from-home policies for all of our employees. While vaccinations beginning in 2021 allowed for the partial reopening of the economy, new variants, as well as reduced efficacy of vaccines over time and the possibility that a large number of people decline to get vaccinated or receive booster shots, creates inherent uncertainty as to the future of our business, our industry and the economy in general in light of the pandemic. Since the beginning of the COVID-19 pandemic, several vaccines for COVID-19 have received Emergency Use Authorization by the FDA and a number 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. The effects of our work-from-home policies may negatively impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. The extent to which the COVID-19 pandemic impacts our operations or those of our third-party partners will depend on future developments, which remain highly uncertain and cannot be predicted with confidence, including the duration of the current Omicron variant, new variants and sub-variants, including the more recent BA.4 and BA.5 sub-variants of the virus which may impact vaccination efforts, mask and vaccine mandates, travel restrictions, and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease, and any additional preventative and protective actions that governments take to contain the COVID-19 pandemic or treat its impact, among others

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 are conducting clinical trials for our product candidates in geographies which continue to be affected by the COVID-19 pandemic. Some factors from the ongoing COVID-19 pandemic that will delay or otherwise adversely affect enrollment in the clinical trials of our product candidates, as well as our business generally, include:

- the 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;
- 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;
- 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, product manufacturing and supply, 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 that enrolled participants will drop out before completion; and
- the FDA and other regulators have made COVID-19 a primary priority, which can result in delays for trials unrelated to the pandemic.

Moreover, COVID-19 may also severely affect employees of third-party CROs located in affected geographies that we rely upon to carry out such enrollments and trials. Such events could cause costly delays to our 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.

These and other factors arising from the ongoing COVID-19 pandemic could worsen as the pandemic continues to evolve. Any of these factors, and other factors related to any unforeseen disruptions, have had and could continue to have a material adverse effect on our business and our results of operation and financial condition. Further, uncertainty around these and related issues has severely harmed and is expected to continue to severely harm the economy of the United States, which could impact our ability to raise the necessary capital needed to develop and commercialize our product candidates.

General Risk Factors

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by economic and political changes in the location in which we, or our suppliers and vendors, maintain operations. For example, our business may be generally exposed to the impact of political or civil unrest or military action, including the current conflict between Russia and Ukraine and, while we do not have direct exposure to Ukraine, we do have third-party manufacturing partners with locations in Europe. The activities of such manufacturing partners may be impacted based upon the events taking place there. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

We are no longer an "emerging growth company" as defined in the JOBS Act, and the reduced disclosure requirements applicable to emerging growth companies no longer apply to us.

As of June 30, 2021, the market value of our common stock that was held by non-affiliates exceeded $700 million, and as a result, as of December 31, 2021, we no longer qualified as an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As such, we will incur significant additional expenses that we did not previously incur in complying with the Sarbanes-Oxley Act of 2002 and rules implemented by the SEC. As a large accelerated filer, we are now subject to certain disclosure requirements that are applicable to other public companies that were not applicable to us as an emerging growth company. These requirements include:

- compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404;
- compliance with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- full disclosure obligations regarding executive compensation; and
- compliance with the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

If we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources. Additionally, we expect that our loss of "emerging growth company" status will require additional attention from management and will result in increased costs to us, which could include higher legal fees, accounting fees and fees associated with investor relations activities, among others.

Risks Related to an Investment in Our Securities

The market price of our stock may be volatile, and you could lose all or part of your investment.

The trading price of our common stock is likely to be volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. During the six months ended June 30, 2022, our stock price has ranged from $8.00 to $22.26. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Quarterly Report on Form 10-Q, these factors include:

- developments associated with our license with Amgen, including any termination or other change in our relationship with Amgen;
- the success of competitive products or technologies;
- regulatory actions with respect to our product candidate or any future product candidates or our competitors' product candidates or products;
- results of clinical trials of our product candidate or any future product candidates or those of our competitors;
- actual or anticipated changes in our growth rate relative to our competitors;

- announcements by us or our competitors or collaborators of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- regulatory, legal or payor developments in the United States 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 product candidate or any future product candidates or clinical development programs;
- the results of our efforts to in-license or acquire additional product candidates or products;
- 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;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or our other stockholders;
- changes in the structure of healthcare payment systems;
- general economic, industry and market conditions, including the ongoing COVID-19 pandemic;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad (such as the ongoing conflict between Ukraine and Russia, including the sanctions imposed by the United States, the European Union and others on Russia and other related parties);
- market conditions in the pharmaceutical and biotechnology sectors; and
- general economic, industry and market conditions.

In addition, the stock market in general, and the market for biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies, including very recently in connection with the ongoing COVID-19 pandemic, which has resulted in decreased stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. Although the markets recovered, market and industry factors, including potentially worsening economic conditions and other adverse effects or developments relating to the ongoing COVID-19 pandemic, may significantly reduce the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this “Risk Factors” section, could have a dramatic and material adverse impact on the market price of our common stock.

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

Holders of stock in companies that have a volatile stock price frequently bring securities class action litigation against the company that issued the stock. We may be the target of this type of litigation in the future. If any of our stockholders were to bring a lawsuit of this type against us, even if the lawsuit is without merit, we could incur substantial costs defending the lawsuit. A stockholder lawsuit could also divert the time and attention of our management. Securities litigation against us could result in substantial costs and divert our management’s attention from other business concerns, which could seriously harm our business.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock.

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

We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and 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 due to error or fraud may occur and not be detected.

If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend, in part, on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on our company. If no securities or industry analysts commence coverage of our company or if they cease to cover our company, the trading price for our stock would likely be negatively impacted. In the event that securities or industry analysts initiate coverage, if one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. In addition, if our operating results fail to meet the forecast of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

Risks Related to Our Charter and Bylaws

Anti-takeover provisions under our organizational 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 fourth amended and restated certificate of incorporation and second 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 the stockholders may 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, and special meetings of stockholders may not be called by any other person or persons;
- 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 (2/3) 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 a majority of all outstanding shares of our voting stock to amend any bylaws by stockholder action and not less than two-thirds (2/3) of all outstanding shares of our voting stock 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, 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, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our fourth amended and restated certificate of incorporation and second 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 amended and restated bylaws designate the Court of Chancery of the State of Delaware 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 amended and restated 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 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 Delaware General Corporation Law, our amended and restated certificate of incorporation or our second amended and restated bylaws (including the interpretation, validity or enforceability thereof), or (iv) any action asserting a claim that is governed by the internal affairs doctrine(the "Delaware Forum Provision"). The Delaware Forum Provision will not apply to any causes of action arising under the Exchange Act. Our amended and restated bylaws further provide that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act (the "Federal Forum Provision"). In addition, our amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock is deemed to have notice of and consented to the Delaware Forum Provision and the Federal Forum Provision; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the U.S. federal securities laws and the rules and regulations thereunder.

The Delaware Forum Provision and the Federal Forum Provision in our bylaws may impose additional litigation costs on stockholders in pursuing any such claims. Additionally, these forum selection clauses may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage the filing of lawsuits against us and our directors, officers and employees, even though an action, if successful, might benefit our stockholders. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court are "facially valid" under Delaware law, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the federal district courts of the United States 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.

Risks Related to Income Taxes

Changes in tax laws 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 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. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations.

We might not be able to utilize a significant portion of our net operating loss carryforwards and research and development tax credit carryforwards.

As of December 31, 2021, we had U.S. federal and state net operating loss, or NOL, carryforwards of $222.4 million and $137.0 million, respectively and federal and state research and development tax credit carryforwards of $5.4 million and $0.6 million, respectively. If not utilized, such NOL carryforwards (other than federal NOL carryforwards arising in taxable years beginning after December 31, 2017) and research and development credits will expire at various dates beginning in 2037 and 2033, respectively. Our ability to use our U.S. federal and state NOL and tax credit carryforwards to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income. We do not anticipate generating revenue from sales of products for the foreseeable future, if ever, and we may never achieve profitability. These NOL and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the current law, federal NOL carryforwards generated in tax years beginning after December 31, 2017 are not subject to expiration. In addition, under Sections 382 of the Code, the amount of benefits from our NOL carryforwards may be impaired or limited if we incur a cumulative ownership change of more than 50% by certain stockholders, as interpreted by the U.S. Internal Revenue Service, over a three-year period. We experienced ownership changes on March 24, 2017, June 7, 2018 and July 8, 2020. We may experience ownership changes again in the future, some of which may be outside our control. As a result, our use of federal NOL and tax credit carryforwards could be limited. State NOL carryforwards may be similarly limited. Any such disallowances may result in greater tax liabilities than we would incur in the absence of such a limitation and any increased liabilities could adversely affect our business, results of operations, financial position and cash flows.

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

During the three and six months ended June 30, 2022, we did not issue or sell any unregistered securities not previously disclosed in a Quarterly Report on Form 10-Q or in a Form 10-K.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

As previously reported in the Company's Current Report on Form 8-K filed with the U.S. Securities and Exchange Commission on June 3, 2022 (the "Original 8-K"), in a non-binding advisory vote held at the 2022 Annual Meeting on the frequency of future say-on-pay votes regarding the compensation of the Company's named executive officers, the Company's stockholders expressed their preference for a say-on-pay vote to be conducted every one year. After taking into consideration the voting results and the prior recommendation of the Company's Board of Directors (the "Board") in favor of an annual stockholder advisory vote on the compensation of the Company's named executive officers, the Board intends to hold future advisory votes on the compensation of the Company's named executive officers every year. The Company's Board will re-evaluate this determination after the next stockholder advisory vote on the frequency of say-on-pay votes (which will be at the 2028 Annual Meeting of Stockholders, unless presented earlier).

Item 6. Exhibits.

EXHIBIT INDEX

Exhibit Number	Exhibit Description
3.1	Fourth Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K (File No. 001-38944) filed on June 24, 2019)
3.2	Amended and Restated Bylaws of the Registrant and the amendments thereto, as currently in effect (incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K (File No. 001-38944) filed on March 12, 2021)
10.1	Securities Purchase Agreement dated June 15, 2022 by and between the Registrant and Pfizer Inc. (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K (File No. 001-38944) filed on June 16, 2022
10.2*#	Loan and Security Agreement dated as of June 15, 2022 by and between the Registrant and Hercules Capital, Inc.
10.3*	Warrant, dated June 15, 2022 by and between the Registrant and Hercules Private Global Venture Growth Fund I L.P.
10.4*	Warrant, dated June 15, 2022 by and between the Registrant and Hercules Capital, Inc.
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 amended
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 amended
32.1+	Certification 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
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.

\# Portions of this exhibit (indicated by asterisks) have been omitted pursuant to Item 601(b)(10) of Regulation S-K.

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.

AKERO THERAPEUTICS, INC.

Date: August 5, 2022 By: /s/ ANDREW CHENG
Andrew Cheng, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 5, 2022 By: /s/ WILLIAM WHITE
William White
Executive Vice President, Chief Financial Officer and
Head of Corporate Development
(Principal Financial and Accounting Officer)

LOAN AND SECURITY AGREEMENT

THIS LOAN AND SECURITY AGREEMENT is made and dated as of June 15, 2022 and is entered into by and among AKERO THERAPEUTICS, INC., a Delaware corporation, and each of its Subsidiaries from time to time party hereto as borrower (individually and collectively referred to as the "Borrower"), the several banks and other financial institutions or entities from time to time parties to this Agreement (collectively, referred to as the "Lenders") and HERCULES CAPITAL, INC., a Maryland corporation, in its capacity as administrative agent and collateral agent for itself and the Lenders (in such capacity, the "Agent").

RECITALS

A. Borrower has requested the Lenders make available to Borrower up to four tranches of term loans in an aggregate principal amount of up to One Hundred Million Dollars ($100,000,000) (the "Term Loans"); and

B. The Lenders are willing to make the Term Loans on the terms and conditions set forth in this Agreement.

AGREEMENT

NOW, THEREFORE, Borrower, Agent and the Lenders agree as follows:

SECTION 1. DEFINITIONS AND RULES OF CONSTRUCTION

1.1 Unless otherwise defined herein, the following capitalized terms shall have the following meanings:

"Account Control Agreement(s)" means any agreement entered into by and among the Agent, Borrower and a third-party bank or other institution (including a Securities Intermediary) in which Borrower maintains a Deposit Account or an account holding Investment Property and which perfects Agent's first priority security interest in the subject account or accounts.

"ACH Authorization" means the ACH Debit Authorization Agreement in substantially the form of Exhibit H, which account numbers shall be redacted for security purposes if and when filed publicly by the Borrower.

"Acquisition" means any transaction or series of related transactions for the purpose of or resulting, directly or indirectly, in (a) the acquisition of all or substantially all of the assets of a Person, or of any business, line of business or division or other unit of operation of a Person, (b) the acquisition of fifty percent (50%) or more of the Equity Interests of any Person, whether or not involving a merger, consolidation or similar transaction with such other Person, or otherwise causing any Person to become a Subsidiary of Borrower, or (c) the acquisition of, or the right to use, develop or sell (in each case, including through licensing (other than "off-the-shelf" licenses)), any product, product line or intellectual property of or from any other Person.

"Advance(s)" means a Term Loan Advance.

"Advance Date" means the funding date of any Advance.

"Advance Request" means a request for an Advance submitted by Borrower to Agent in substantially the form of Exhibit A, which account numbers shall be redacted for security purposes if and when filed publicly by the Borrower.

"Affiliate" means (a) any Person that directly or indirectly controls, is controlled by, or is under common control with the Person in question, (b) any Person directly or indirectly owning, controlling or holding with power to vote ten percent (10%) or more of the outstanding voting securities of another Person, (c) any Person ten percent (10%) or more of whose outstanding voting securities are directly or indirectly owned, controlled or held by another Person with power to vote such securities, or (d) any Person related by blood or marriage to any Person described in subsection (a), (b) or (c) of this paragraph. As used in the definition of "Affiliate," the term "control" means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of a Person, whether through ownership of voting securities, by contract or otherwise.

"Agreement" means this Loan and Security Agreement, as amended, restated, amended and restated, supplemented or otherwise modified from time to time.

"Akero Therapeutics" means Akero Therapeutics, Inc., a Delaware corporation.

"Amgen License" means that certain License Agreement dated June 7, 2018 by and between Amgen Inc. and Akero Therapeutics, as amended, restated, supplemented or otherwise modified from time to time.

"Amortization Date" means July 1, 2024; provided however, if the Interest Only Extension Conditions are satisfied, then July 1, 2025.

"Anti-Corruption Laws" means all laws, rules, and regulations of any jurisdiction applicable to Borrower or any of its Affiliates from time to time concerning or relating to bribery or corruption, including without limitation the United States Foreign Corrupt Practices Act of 1977, as amended, the UK Bribery Act 2010 and other similar legislation in any other jurisdictions.

"Anti-Terrorism Laws" means any laws, rules, regulations or orders relating to terrorism or money laundering, including without limitation Executive Order No. 13224 (effective September 24, 2001), the USA PATRIOT Act, the laws comprising or implementing the Bank Secrecy Act, and the laws administered by OFAC.

"Blocked Person" means any Person: (a) listed in the annex to, or is otherwise subject to the provisions of, Executive Order No. 13224, (b) a Person owned or controlled by, or acting for or on behalf of, any Person that is listed in the annex to, or is otherwise subject to the provisions of, Executive Order No. 13224, (c) a Person with which any Lender is prohibited from dealing or otherwise engaging in any transaction by any Anti-Terrorism Law, (d) a Person that commits, threatens or conspires to commit or supports "terrorism" as defined in Executive Order No. 13224, or (e) a Person that is named a "specially designated national" or "blocked person" on the most current list published by OFAC or other similar list.

"Borrower Products" means all products, software, service offerings, technical data or technology currently being designed, manufactured or sold by Borrower or which Borrower intends to sell,

license, or distribute in the future including any products or service offerings under development, collectively, together with all products, software, service offerings, technical data or technology that have been sold, licensed or distributed by Borrower since its formation.

"Borrower's Books" means Borrower's or any of its Subsidiaries' books and records including ledgers, federal, state, local and foreign tax returns, records regarding Borrower's or its Subsidiaries' assets or liabilities, the Collateral, business operations or financial condition, and all computer programs or storage or any equipment containing such information.

"Business Day" means any day other than Saturday, Sunday and any other day on which banking institutions in the State of California are closed for business.

"Cash" means all cash, cash equivalents and liquid funds.

[***]

"Change in Control" means any (x) reorganization, recapitalization, consolidation or merger (or similar transaction or series of related transactions) of Akero Therapeutics, sale or exchange of outstanding shares (or similar transaction or series of related transactions) of Akero Therapeutics in which the holders of Akero Therapeutics' outstanding shares immediately before consummation of such transaction or series of related transactions do not, immediately after consummation of such transaction or series of related transactions, retain shares representing more than fifty percent (50%) of the voting power of the surviving entity of such transaction or series of related transactions (or the parent of such surviving entity if such surviving entity is wholly owned by such parent), in each case without regard to whether Akero Therapeutics is the surviving entity or (y) "change of control", "fundamental change", "make-whole fundamental change" or any comparable term under and as defined in any indenture governing any Permitted Convertible Debt Financing has occurred.

"Closing Date" means the date of this Agreement.

"Code" means the Internal Revenue Code of 1986, as amended.

"Common Stock" means the Common Stock of Akero Therapeutics.

"Contingent Obligation" means, as applied to any Person, any direct or indirect liability, contingent or otherwise, of that Person with respect to (i) any Indebtedness, lease (excluding operating leases of real property), dividend, letter of credit or other obligation of another, including any such obligation directly or indirectly guaranteed, endorsed, co-made or discounted or sold with recourse by that Person, or in respect of which that Person is otherwise directly or indirectly liable; (ii) any obligations with respect to undrawn letters of credit, corporate credit cards or merchant services issued for the account of that Person; and (iii) all obligations arising under any interest rate, currency or commodity swap agreement, interest rate cap agreement, interest rate collar agreement, or other agreement or arrangement designated to protect a Person against fluctuation in interest rates, currency exchange rates or commodity prices; provided, however, that the term "Contingent Obligation" shall not include endorsements for collection or deposit in the ordinary course of business. The amount of any Contingent Obligation shall be deemed, without duplication of the primary obligation, to be an amount equal to the stated or determined amount of the primary obligation in respect of which such Contingent Obligation is made or, if not stated or determinable, the maximum reasonably anticipated liability in respect thereof as determined by such Person in good faith; provided, however, that such amount shall not in any event exceed the maximum amount of the obligations under the guarantee or other support arrangement.

"Copyright License" means any written agreement granting any right to use any Copyright or Copyright registration, now owned or hereafter acquired by Borrower or in which Borrower now holds or hereafter acquires any interest.

"Copyrights" means all copyrights, whether registered or unregistered, held pursuant to the laws of the United States of America, any State thereof, or of any other country.

"Default" means any event, circumstance or condition that has occurred or exists, that would, with the passage of time or the requirement that notice be given or both, become an Event of Default.

"Deposit Accounts" means any "deposit accounts," as such term is defined in the UCC, and includes any checking account, savings account, or certificate of deposit.

"Disqualified Equity Interests" means any Equity Interests that, by their terms (or by the terms of any security or other Equity Interests into which they are convertible or for which they are exchangeable), or upon the happening of any event or condition (a) mature or are mandatorily redeemable (other than solely for Qualified Equity Interests) pursuant to a sinking fund obligation or otherwise on or prior to one hundred eighty (180) days following the Term Loan Maturity Date at the time such Equity Interests are issued (it being understood that if any such redemption is in part, only such part coming into effect prior to one hundred eighty (180) days following the Term Loan Maturity Date shall constitute Disqualified Equity Interests) (except as a result of a change of control or asset sale so long as any rights of the holders thereof upon the occurrence of a change of control or asset sale event shall be subject to the prior repayment in full of the Secured Obligations), (b) are redeemable at the option (except as a result of a change of control or asset sale so long as any rights of the holders thereof upon the occurrence of a change of control or asset sale event shall be subject to the prior repayment in full of the Secured Obligations) of the holder thereof (other than solely for Qualified Equity Interests), in whole or in part, on or prior to one hundred eighty (180) days following the Term Loan Maturity Date at the time such Equity Interests are issued, (c) provide for scheduled payments of dividends in cash or cash equivalents on or prior to one hundred eighty (180) days following the Term Loan Maturity Date at the time such Equity Interests are issued, or (d) are or become convertible into or exchangeable for Indebtedness or any other Equity Interests that would constitute Disqualified Equity Interests, in each case, prior to the date that is one hundred eighty (180) days after the Term Loan Maturity Date.

"Domestic Subsidiary" means any Subsidiary organized under the laws of the United States of America, any State thereof, the District of Columbia, or any other jurisdiction within the United States of America.

"Due Diligence Fee" means Fifty Thousand Dollars ($50,000), which fee has been paid to the Agent prior to the Closing Date, and shall be deemed fully earned on such date regardless of the early termination of this Agreement.

"EFX Trial" means the randomized, double-blind, placebo-controlled HARMONY clinical trial sponsored by Borrower to evaluate the safety and effectiveness of efruxifermin in non-cirrhotic subjects with non-alcoholic steatohepatitis (NASH).

"Equity Interests" means, with respect to any Person, the capital stock, partnership or limited liability company interest, or other equity securities or equity ownership interests of such Person.

"ERISA" means the Employee Retirement Income Security Act of 1974, as amended, and the regulations promulgated thereunder.

"Excluded Accounts" means (a) Deposit Accounts exclusively used for payroll, payroll taxes, and other employee wage and benefit payments to or for the benefit of Borrower's employees holding an aggregate amount across all such accounts of not more than amounts needed for the then-next two (2) payroll cycles and (b) any accounts held by MSC Subsidiary.

"Facility Charge" means 0.50% of the principal amount of any Advance (other than a Tranche I Advance), which is payable to the Lenders in accordance with Section 4.2(d).

"FDA" means the U.S. Food and Drug Administration or any successor thereto.

"Foreign Subsidiary" means any Subsidiary other than a Domestic Subsidiary.

"FSHCO" means any Domestic Subsidiary (including any disregarded entity for U.S. federal income tax purposes), substantially all of the assets of which consist of, directly or indirectly, Equity Interests in (or Equity Interests in and indebtedness of) one or more "controlled foreign corporation" within the meaning of Section 957 of the Code.

"GAAP" means generally accepted accounting principles in the United States of America, as in effect from time to time.

"Indebtedness" means indebtedness of any kind, including (a) all indebtedness for borrowed money or the deferred purchase price of property or services (excluding trade credit entered into in the ordinary course of business due within ninety (90) days), including reimbursement and other obligations with respect to surety bonds and letters of credit, (b) all obligations evidenced by notes, bonds, debentures or similar instruments, (c) all capital lease obligations, (d) all equity securities of any Person subject to repurchase or redemption other than at the sole option of such Person, (e) "earnouts", purchase price adjustments, profit sharing arrangements, deferred purchase money amounts and similar payment obligations or continuing obligations of any nature arising out of purchase and sale contracts, (f) obligations arising under bonus, deferred compensation, incentive compensation or similar arrangements (other than those arising in the ordinary course of business), (g) non-contingent obligations to reimburse any bank or Person in respect of amounts paid under a letter of credit, banker's acceptance or similar instrument, and (h) all Contingent Obligations.

"Initial Facility Charge" means a charge of One Hundred Thousand Dollars ($100,000).

"Intellectual Property" means all of Borrower's Copyrights; Trademarks; Patents; Licenses; trade secrets and inventions; mask works; Borrower's applications therefor and reissues, extensions, or renewals thereof; and Borrower's goodwill associated with any of the foregoing, together with Borrower's rights to sue for past, present and future infringement of Intellectual Property and the goodwill associated therewith.

"Interest Only Extension Conditions" shall mean satisfaction of each of the following events: (a) no Default or Event of Default shall have occurred and is continuing; and (b) the Tranche III Milestone Date has occurred.

"Investment" means (a) any beneficial ownership (including stock, partnership, interests, limited liability company interests, or other securities) of or in any Person, (b) any loan, advance or capital contribution to any Person, (c) any Acquisition or (d) other transfers on behalf of or in connection with any equity ownership or similar transfers.

"IRS" means the United States Internal Revenue Service.

"Joinder Agreements" means for each Subsidiary, a completed and executed Joinder Agreement in substantially the form attached hereto as Exhibit F.

"License" means any Copyright License, Patent License, Trademark License or other Intellectual Property license of rights or interests.

"Lien" means any mortgage, deed of trust, pledge, hypothecation, assignment for security, security interest, encumbrance, levy, lien or charge of any kind, whether voluntarily incurred or arising by operation of law or otherwise, against any property, any conditional sale or other title retention agreement, and any lease in the nature of a security interest.

"Loan" means the Advances made under this Agreement.

"Loan Documents" means this Agreement, the promissory notes (if any), the ACH Authorization, the Account Control Agreements, any Joinder Agreements, all UCC Financing Statements, the Warrant and any other documents executed in connection with the Secured Obligations or the transactions contemplated hereby, as the same may from time to time be amended, modified, supplemented or restated.

"Material Adverse Effect" means a material adverse effect upon: (i) the business, operations, properties, assets or financial condition of Borrower and its Subsidiaries taken as a whole; or (ii) the ability of Borrower to perform or pay the Secured Obligations in accordance with the terms of the Loan Documents, or the ability of Agent or the Lenders to enforce any of its rights or remedies with respect to the Secured Obligations; or (iii) the Collateral or Agent's Liens on the Collateral or the priority of such Liens.

"Material Agreement" means (a) the Amgen License, (b) the Master Services Agreement between Akero Therapeutics and Labcrop Drug Development Inc. f/k/a Covance, Inc. (as amended, restated, amended and restated, supplemented or otherwise modified from time to time), (c) the Master Services Agreement between Akero Therapeutics and Medpace, Inc. (as amended, restated, amended and restated, supplemented or otherwise modified from time to time), (d) the Master Services Agreement between Akero Therapeutics and Vetter Pharma International GmbH (as amended, restated, amended and restated, supplemented or otherwise modified from time to time), (e) the Technology Transfer and Clinical Supply Agreement between Akero Therapeutics and Boehringer Ingelheim Biopharmaceutical GmbH (as amended, restated, amended and restated, supplemented or otherwise modified from time to time), and (f) any license, agreement or other contractual arrangement involving the receipt or payment of amounts in the aggregate exceeding Five Hundred Thousand Dollars ($500,000) per fiscal year.

"Maximum Term Loan Amount" means One Hundred Million Dollars ($100,000,000).

"MSC Investment Conditions" means that Borrower maintains Qualified Cash in an amount equal to or greater than the lesser of (i) one hundred and ten percent (110%) of the aggregate outstanding Secured Obligations (inclusive of any Prepayment Charge and End of Term Charge that would be due and owing if the outstanding Loans were prepaid at the time of measurement) or (ii) one hundred percent (100%) of the consolidated Cash of Borrower and its Subsidiaries, unless compliance with the foregoing conditions are waived in writing from time to time by Agent (in its sole discretion) with respect to specified periods.

"MSC Subsidiary" means Akero Securities Corporation, a wholly-owned Subsidiary incorporated in the Commonwealth of Massachusetts or the State of Delaware for the purpose of holding Investments as a Massachusetts security corporation under 830 CMR 63.38B.1 of the Massachusetts tax code and applicable regulations (as the same may be amended, modified or replaced from time to time).

"Non-Core Intellectual Property" means any Intellectual Property not material to Borrower's business upon prior consultation with Agent.

"Non-Disclosure Agreement" means that certain Non-Disclosure Agreement by and between Agent and Borrower dated as of March 31, 2022.

"OFAC" means the U.S. Department of Treasury Office of Foreign Assets Control.

"OFAC Lists" means, collectively, the Specially Designated Nationals and Blocked Persons List maintained by OFAC pursuant to Executive Order No. 13224, 66 Fed. Reg. 49079 (Sept. 25, 2001) and/or any other list of terrorists or other restricted Persons maintained pursuant to any of the rules and regulations of OFAC or pursuant to any other applicable Executive Orders.

"Patent License" means any written agreement granting any right with respect to any invention on which a Patent is in existence or a Patent application is pending, in which agreement Borrower now holds or hereafter acquires any interest.

"Patents" means all letters patent of, or rights corresponding thereto, in the United States of America or in any other country, all registrations and recordings thereof, and all applications for letters patent of, or rights corresponding thereto, in the United States of America or any other country.

"Perfection Certificate" means a completed certificate entitled "Perfection Certificate" delivered by Borrower to Agent and the Lenders, signed by Borrower.

"Permitted Convertible Debt Financing" means issuance by Akero Therapeutics of convertible notes in an aggregate principal amount of not more than Two Hundred Million Dollars ($200,000,000); provided that such convertible notes shall (a) both immediately prior to and immediately after giving effect (including pro forma effect) thereto, no Default or Event of Default shall exist or result therefrom, (b) have no scheduled amortization or principal payments, mandatory redemptions or other required payments of principal prior to the date that is one hundred eighty (180) days after the Term Loan Maturity Date, other than customary payments upon a "change of control", "fundamental change", "make-whole fundamental change" or any comparable term (it being understood that a holder's option to convert any such Indebtedness into Common Stock (and Cash in lieu of fractional shares) shall not be considered a required mandatory redemption or payment of principal), (c) be unsecured, (d) not be guaranteed by any Subsidiary of Akero Therapeutics that is not a Borrower, (e) contain usual and customary subordination terms for underwritten offerings of senior subordinated convertible notes as reasonably determined in good faith by Borrower's Board of Directors or a committee thereof, (f) shall be Indebtedness of Akero Therapeutics and not of any Subsidiary thereof, and (g) shall specifically designate this Agreement and all Secured Obligations as "designated senior indebtedness" or similar term so that the subordination terms referred to in clause (d) of this definition specifically refer to such notes as being subordinated to the Secured Obligations pursuant to such subordination terms. For the avoidance of doubt, Permitted Convertible Debt Financing shall not constitute Subordinated Indebtedness.

"Permitted Indebtedness" means:

(i) Indebtedness of Borrower in favor of any Lender or Agent arising under this Agreement or any other Loan Document;

(ii) Indebtedness existing on the Closing Date which is disclosed in Schedule 1A;

(iii) Indebtedness of up to Two Hundred Fifty Thousand Dollars ($250,000) outstanding at any time secured by a Lien described in clause (vii) of the defined term "Permitted Liens," provided such Indebtedness does not exceed the cost of the Equipment or software or other intellectual property financed with such Indebtedness;

(iv) Indebtedness to trade creditors incurred in the ordinary course of business (due within ninety (90) days), including such Indebtedness incurred in the ordinary course of business with corporate credit cards in an amount not to exceed One Million Dollars ($1,000,000) at any time outstanding;

(v) Indebtedness that also constitutes a Permitted Investment or is secured by a Permitted Lien;

(vi) Subordinated Indebtedness;

(vii) reimbursement obligations in connection with letters of credit that are secured by Cash and issued on behalf of the Borrower or a Subsidiary in an amount not to exceed Two Hundred Thousand Dollars ($200,000) at any time outstanding,

(viii) the Permitted Convertible Debt Financing;

(ix) Indebtedness with respect to a Permitted Royalty Transaction that (a) is subordinated to the Secured Obligations pursuant to a subordination or intercreditor agreement on terms and conditions reasonably satisfactory to Agent, and (b) does not have a scheduled maturity date earlier than one hundred eighty (180) days after the Term Loan Maturity Date;

(x) intercompany Indebtedness as long as either (A) each of the Subsidiary obligor and the Subsidiary obligee under such Indebtedness is a Subsidiary that has executed a Joinder Agreement or (B) each of the obligor and obligee are Foreign Subsidiaries;

(xi) Indebtedness incurred to finance insurance premiums in the ordinary course of business;

(xii) Indebtedness incurred as a result of endorsing negotiable instruments received in the ordinary course of business;

(xiii) security deposit obligations in connection with the lease of real property in an amount not to exceed Five Hundred Thousand Dollars ($500,000) at any time outstanding;

(xiv) other unsecured Indebtedness in an amount not to exceed Five Hundred Thousand Dollars ($500,000) at any time outstanding; and

(xv) extensions, refinancings and renewals of any items of Permitted Indebtedness, provided that the principal amount is not increased or the terms modified to impose materially more burdensome terms upon Borrower or its Subsidiary, as the case may be, and subject to any limitations on aggregate amount of such Indebtedness.

"Permitted Investment" means:

(i) Investments existing on the Closing Date which are disclosed in Schedule 1B;

(ii) (a) marketable direct obligations issued or unconditionally guaranteed by the United States of America or any agency or any State thereof maturing within one year from the date of acquisition thereof currently having a rating of at least A-2 or P-2 from either Standard & Poor's Corporation or Moody's Investors Service, (b) commercial paper maturing no more than one year from the date of creation thereof and currently having a rating of at least A-2 or P-2 from either Standard & Poor's Corporation or Moody's Investors Service, (c) certificates of deposit issued by any bank with assets of at least Five Hundred Million Dollars ($500,000,000) maturing no more than one year from the date of investment therein, (d) money market accounts, and (e) Investments made in accordance with Borrower's investment policy, dated as of March 24, 2020 in the form delivered to Agent prior to the Closing Date (as amended or otherwise modified from time to time so long as Agent consents in writing to such investment policy);

(iii) repurchases of stock of Borrower from former or existing employees, officers, directors, or consultants of Borrower under the terms of applicable repurchase agreements or other similar agreements at the original issuance price of such securities in an aggregate amount not to exceed Two Hundred Fifty Thousand Dollars ($250,000) in any fiscal year, provided that no Event of Default has occurred, is continuing or would exist after giving effect to the repurchases;

(iv) Investments accepted in connection with Permitted Transfers;

(v) Investments (including debt obligations) received in connection with the bankruptcy or reorganization of customers or suppliers and in settlement of delinquent obligations of, and other disputes with, customers or suppliers arising in the ordinary course of Borrower's business;

(vi) Investments consisting of notes receivable of, or prepaid royalties and other credit extensions, to customers and suppliers who are not Affiliates, in the ordinary course of business, provided that this subparagraph (vi) shall not apply to Investments of Borrower in any Subsidiary;

(vii) Investments consisting of loans not involving the net transfer on a substantially contemporaneous basis of cash proceeds to employees, officers or directors relating to the purchase of capital stock of Borrower pursuant to employee stock purchase plans or other similar agreements approved by Borrower's Board of Directors;

(viii) Investments consisting of: (A) travel advances and employee relocation loans in the ordinary course of business, and (B) loans to employees, officers, managers or directors relating to the purchase of equity securities of Borrower or its Subsidiaries pursuant to employee stock purchase plans or agreements approved by Borrower's or its Subsidiary's Board of Directors or similar governing body; not to exceed Five Hundred Thousand Dollars ($500,000) in the aggregate for (A) and (B) from the Closing Date until the time that no Secured Obligations (other than for inchoate indemnification obligations) remain outstanding;

(ix) Investments in newly-formed Subsidiaries (other than the MSC Subsidiary), provided that each such Subsidiary enters into a Joinder Agreement promptly after its formation and executes such other documents as shall be reasonably requested by Agent;

(x) Investments in the MSC Subsidiary, so long as an Event of Default does not exist at the time of such Investment and would not exist after giving effect to such Investment and provided that Borrower is, at all times, in compliance with the MSC Investment Conditions;

(xi) Investments in Foreign Subsidiaries approved in advance in writing by Agent;

(xii) joint ventures or strategic alliances in the ordinary course of Borrower's business consisting of the nonexclusive licensing of technology, the development of technology or the providing of technical support, provided that any cash Investments by Borrower do not exceed [***] in any fiscal year;

(xiii) Investments made in connection with [***] provided that (A) the Tranche II Milestone Date has occurred and (B) such Investments under this clause (xiii) do not exceed Two Million Five Hundred Thousand Dollars ($2,500,000) in the aggregate at any time; and

(xiv) additional Investments that do not exceed Two Hundred Fifty Thousand Dollars ($250,000) in the aggregate.

"Permitted Liens" means:

(i) Liens in favor of Agent or the Lenders;

(ii) Liens existing on the Closing Date which are disclosed in Schedule 1C;

(iii) Liens for taxes, fees, assessments or other governmental charges or levies, either not yet due or being contested in good faith by appropriate proceedings diligently conducted; provided, that Borrower maintains adequate reserves therefor on Borrower's Books in accordance with GAAP;

(iv) Liens securing claims or demands of materialmen, artisans, mechanics, carriers, warehousemen, landlords and other like Persons arising in the ordinary course of Borrower's business and imposed without action of such parties; provided, that the payment thereof is not yet required;

(v) Liens arising from judgments, decrees or attachments in circumstances which do not constitute an Event of Default hereunder;

(vi) the following deposits, to the extent made in the ordinary course of business: deposits under worker's compensation, unemployment insurance, social security and other similar laws, or to secure the performance of bids, tenders or contracts (other than for the repayment of borrowed money) or to secure indemnity, performance or other similar bonds for the performance of bids, tenders or contracts (other than for the repayment of borrowed money) or to secure statutory obligations (other than Liens arising under ERISA or environmental Liens) or surety or appeal bonds, or to secure indemnity, performance or other similar bonds;

(vii) Liens on Equipment or software or other intellectual property constituting purchase money Liens and other Liens in connection with capital leases securing Indebtedness permitted in clause (iii) of "Permitted Indebtedness";

(viii) Liens incurred in connection with Subordinated Indebtedness;

(ix) leasehold interests in leases or subleases and licenses granted in the ordinary course of business and not interfering in any material respect with the business of the licensor;

(x) Liens in favor of customs and revenue authorities arising as a matter of law to secure payment of custom duties that are promptly paid on or before the date they become due;

(xi) Liens on insurance proceeds securing the payment of financed insurance premiums that are promptly paid on or before the date they become due (provided that such Liens extend only to such insurance proceeds and not to any other property or assets);

(xii) statutory and common law rights of set-off and other similar rights as to deposits of cash and securities in favor of banks, other depository institutions and brokerage firms;

(xiii) easements, servitudes, zoning restrictions, rights-of-way and similar encumbrances on real property imposed by law or arising in the ordinary course of business so long as they do not materially impair the value or marketability of the related property;

(xiv) Liens solely on the royalty interests purchased pursuant to a Permitted Royalty Transaction and proceeds thereon; provided that no Liens shall be granted with respect to any Intellectual Property of Borrower or its Subsidiaries;

(xv) (A) Liens on Cash or government securities securing obligations permitted under clause (vii) of the definition of Permitted Indebtedness and (B) security deposits in connection with real property leases, the combination of (A) and (B) in an aggregate amount not to exceed Five Hundred Thousand Dollars ($500,000) at any time;

(xvi) Licenses that qualify as Permitted Transfers;

(xvii) customary Liens in favor of any financial institution in connection with statutory, common law and contractual rights of setoff and recoupment with respect to any Deposit Accounts and/or securities accounts of Borrower held at such institution, provided that (A) Agent has a first priority perfected security interest in such account and (B) such account is permitted to be maintained pursuant to Section 7.12; and

(xviii) Liens incurred in connection with the extension, renewal or refinancing of the Indebtedness secured by Liens of the type described in clauses (i) through (xvi) above; provided, that any extension, renewal or replacement Lien shall be limited to the property encumbered by the existing Lien and the principal amount of the Indebtedness being extended, renewed or refinanced (as may have been reduced by any payment thereon) does not increase.

"Permitted Royalty Transaction" means any royalty or revenue interest financing whereby Borrower receives upfront unrestricted (including, not subject to any redemption, clawback, escrow or similar encumbrance or restriction) net cash proceeds of no less than [***] in exchange for rights to receive future payments based on net sales or revenue, as applicable, in an amount not to exceed, in the aggregate for all such Permitted Royalty Transactions, [***] of worldwide net sales or revenue, as applicable, in any calendar year, provided that such royalty or revenue interest financing shall be on terms and conditions, and with a purchaser, in each case consented to in writing by Agent. Notwithstanding anything herein to the contrary, subject to such consent in writing by Agent, a Permitted Royalty Transaction may be structured on a non-recourse basis (other than customary securitization undertakings and/or a pledge of special purpose entity stock) with a special purpose entity that is a wholly owned Subsidiary of Borrower, and in

such case Agent and Lenders shall enter into further amendments to the Loan Documents as are reasonably requested by Borrower to give effect to such Permitted Royalty Transactions.

"Permitted Transfers" means:

(i) sales of Inventory in the ordinary course of business,

(ii) licenses and similar arrangements for the use of Intellectual Property in the ordinary course of business and on an arms' length basis, including in connection with business development transactions, co-development or co-promotion transactions, collaborations, licensing, partnering or similar transactions with third parties and that are entered into with commercially reasonable terms, that could not result in a legal transfer of title of the licensed property that may be either (a) exclusive in respects other than territory, or (b) exclusive as to territory but only as to (x) discrete geographical areas outside of the United States of America or (y) for Non-Core Intellectual Property;

(iii) dispositions of worn-out, obsolete or surplus Equipment at fair market value in the ordinary course of business,

(iv) use or Transfer of Cash in the ordinary course of business in a manner not prohibited by the terms of this Agreement;

(v) Transfers by and among Borrower and any Subsidiary that has executed a Joinder Agreement;

(vi) constituting the making of Permitted Investments, or the granting of Permitted Liens;

(vii) Transfers consisting of royalty payments in connection with any Permitted Royalty Transaction;

(viii) sale or issuance of Equity Interests of Akero Therapeutics in the ordinary course of business in a manner not prohibited by the terms of this Agreement; and

(ix) other Transfers of assets having a fair market value of not more than Five Hundred Thousand Dollars ($500,000) in the aggregate in any fiscal year.

"Person" means any individual, sole proprietorship, partnership, joint venture, trust, unincorporated organization, association, corporation, limited liability company, institution, other entity or government.

"Pfizer Financing" means the strategic financing arrangement entered into between Pfizer Inc. or its Affiliate ("Pfizer Counterparty") and Akero Therapeutics after the Closing Date pursuant to which the Pfizer Counterparty shall provide funds to Akero Therapeutics in exchange for a private sale or issuance of Qualified Equity Interests in Akero Therapeutics to the Pfizer Counterparty.

"Qualified Cash" means an amount equal to (a) the amount of Borrower's Cash held in accounts subject to an Account Control Agreement in favor of Agent, *minus* (b) the Qualified Cash A/P Amount.

"Qualified Cash A/P Amount" means the amount of Borrower's accounts payable under GAAP not paid after the 90th day following the invoice for such account payable.

"Qualified Equity Interests" means any Equity Interests that are not Disqualified Equity Interests.

"Qualified Equity Issuance Net Proceeds" means the net proceeds in Cash (excluding any conversion of existing notes, share repurchases, or other holdbacks or discounts) received by Akero Therapeutics as consideration for any (a) public or private sale or issuance of any Qualified Equity Interests of Akero Therapeutics, (b) contribution to the equity capital of Akero Therapeutics (other than in exchange for Disqualified Equity Interests), (c) sale or issuance of Indebtedness of Akero Therapeutics (other than intercompany Indebtedness) that has been converted into or exchanged for Qualified Equity Interests of Akero Therapeutics and which constitutes a Permitted Convertible Debt Financing, (d) interest, returns, profits, dividends, distributions and similar amounts received in connection with a Permitted Royalty Transaction, (d) sale or issuance of Subordinated Indebtedness, or (e) entry into a development and commercialization agreement relating to a product candidate of Borrower; provided that the amount of Cash received by Akero Therapeutics is, (i) in the case of clauses (a) and (b) above, measured at the time made and without adjustment for subsequent changes in value, payable for the fair market value of sale, issuance or contribution and any other property received in connection with such sale, issuance or contribution, and paid by any Person that is not Borrower or its Subsidiary, and (ii) in the case of clause (c) above, the aggregate principal amount of Indebtedness so converted or exchanged.

"Qualified Pfizer Net Proceeds" means the net proceeds in Cash (excluding any conversion of existing notes, share repurchases, or other holdbacks or discounts) received by Akero Therapeutics from, or at the direction of, the Pfizer Counterparty as consideration for the Pfizer Financing, as measured at the time made and without adjustment for subsequent changes in value, payable for the fair market value of sale or issuance and any other property received in connection with such sale or issuance.

"Receivables" means (i) all of Borrower's Accounts, Instruments, Documents, Chattel Paper, Supporting Obligations, letters of credit, proceeds of any letter of credit, and Letter of Credit Rights, and (ii) all customer lists, software, and business records related thereto.

"Register" has the meaning specified in Section 11.7.

"Required Lenders" means at any time, the holders of more than fifty percent (50%) of the sum of the aggregate unpaid principal amount of the Term Loan Advances then outstanding.

"Restricted License" means any material License or other material agreement with respect to which Borrower is the licensee (a) that prohibits or otherwise restricts Borrower from granting a security interest in Borrower's interest in such License or agreement or any other property, or (b) for which a default under or termination of could interfere with the Agent's right to sell any Collateral. For the avoidance of doubt, "Restricted License" does not include any commercially available or open-source software.

"Sanctioned Country" means, at any time, a country or territory which is the subject or target of any Sanctions.

"Sanctioned Person" means, at any time, (a) any Person listed in any Sanctions-related list of designated Persons maintained by the Office of Foreign Assets Control of the U.S. Department of the Treasury or the U.S. Department of State, or by the United Nations Security Council, the European Union or any EU member state, (b) any Person operating, organized or resident in a Sanctioned Country or (c) any Person controlled by any such Person.

"Sanctions" means economic or financial sanctions or trade embargoes imposed, administered or enforced from time to time by (a) the U.S. government, including those administered by the Office of Foreign Assets Control of the U.S. Department of the Treasury or the U.S. Department of State, or (b) the United Nations Security Council, the European Union or Her Majesty's Treasury of the United Kingdom.

"SBA Funding Date" means each date on which a Lender which is an SBIC funds any portion of the Term Loans.

"Secured Obligations" means Borrower's obligations under this Agreement and any Loan Document (other than the Warrant), including any obligation to pay any amount now owing or later arising.

"Subordinated Indebtedness" means Indebtedness subordinated to the Secured Obligations in amounts and on terms and conditions satisfactory to Agent in its sole discretion and subject to a subordination agreement in form and substance satisfactory to Agent in its sole discretion.

"Subsequent Financing" means the closing of any Borrower financing that is broadly marketed to multiple investors after the Closing Date.

"Subsidiary" means an entity, whether a corporation, partnership, limited liability company, joint venture or otherwise, in which Borrower owns or controls, either directly or indirectly, fifty percent (50%) or more of the outstanding voting securities, including each entity listed on Schedule 1 hereto.

"Taxes" means all present or future taxes, levies, imposts, duties, deductions, withholdings (including backup withholding), assessments, fees or other charges imposed by any governmental authority, including any interest, additions to tax or penalties applicable thereto.

"Term Commitment" means as to any Lender, the obligation of such Lender, if any, to make a Term Loan Advance to Borrower in a principal amount not to exceed the amount set forth under the heading "Term Commitment" opposite such Lender's name on Schedule 1.1.

"Term Loan Advance" means each Tranche I Advance, Tranche II Advance, Tranche III Advance, Tranche IV Advance and any other Term Loan funds advanced under this Agreement.

"Term Loan Interest Rate" means for any day a per annum rate of interest equal to the greater of either (i) (x) the prime rate as reported in The Wall Street Journal *plus* (y) three and thirteen-twentieths of one percent (3.65%), and (ii) seven and thirteen-twentieths of one percent (7.65%).

"Term Loan Maturity Date" means January 1, 2027; provided that if such day is not a Business Day, the Term Loan Maturity Date shall be the immediately preceding Business Day.

"Trademark License" means any written agreement granting any right to use any Trademark or Trademark registration, now owned or hereafter acquired by Borrower or in which Borrower now holds or hereafter acquires any interest.

"Trademarks" means all trademarks (registered, common law or otherwise) and any applications in connection therewith, including registrations, recordings and applications in the United States Patent and Trademark Office or in any similar office or agency of the United States of America, any State thereof or any other country or any political subdivision thereof.

"Tranche II Milestone Date" means the date on which Agent receives evidence reasonably satisfactory to Agent that each of the following events have occurred: [***].

"Tranche III Milestone Date" means the date on which Agent receives evidence reasonably satisfactory to Agent that each of the following events have occurred: [***].

"UCC" means the Uniform Commercial Code as the same is, from time to time, in effect in the State of California; provided, that in the event that, by reason of mandatory provisions of law, any or all of the attachment, perfection or priority of, or remedies with respect to, Agent's Lien on any Collateral is governed by the Uniform Commercial Code as the same is, from time to time, in effect in a jurisdiction other than the State of California, then the term "UCC" shall mean the Uniform Commercial Code as in effect, from time to time, in such other jurisdiction solely for purposes of the provisions thereof relating to such attachment, perfection, priority or remedies and for purposes of definitions related to such provisions.

"U.S. Person" means any Person that is a "United States person" as defined in Section 7701(a)(30) of the Code.

"Warrant" means any warrant entered into in connection with the Loan, as may be amended, restated or modified from time to time.

1.1 The following terms are defined in the Sections or subsections referenced opposite such terms:

Defined Term	Section
Agent	Preamble
Assignee	11.14
Borrower	Preamble
Claims	11.11(a)
Collateral	3.1
Confidential Information	11.13
End of Term Charge	2.5
Event of Default	9
Financial Statements	7.1
Indemnified Person	6.3
Lenders	Preamble
Liabilities	6.3
Maximum Rate	2.2
Participant Register	11.8
Pfizer Counterparty	1.1
Prepayment Charge	2.4
Publicity Materials	11.19
Register	11.7
Rights to Payment	3.1
SBA	7.16
SBIC	7.16
SBIC Act	7.16
Tranche I Advances	2.1(a)
Tranche II Advances	2.1(a)
Tranche III Advances	2.1(a)
Tranche IV Advances	2.1(a)
Transfer	7.8

1.2 Unless otherwise specified, all references in this Agreement or any Annex or Schedule hereto to a "Section," "subsection," "Exhibit," "Annex," or "Schedule" shall refer to the corresponding Section, subsection, Exhibit, Annex, or Schedule in or to this Agreement. Unless otherwise specifically provided herein, any accounting term used in this Agreement or the other Loan Documents shall have the meaning customarily given such term in accordance with GAAP as in effect on the date hereof, and all financial computations hereunder shall be computed in accordance with GAAP as in effect on the date hereof, consistently applied. Unless otherwise defined herein or in the other Loan Documents, terms that are used herein or in the other Loan Documents and defined in the UCC shall have the meanings given to them in the UCC. For all purposes under the Loan Documents, in connection with any division or plan of division under Delaware law (or any comparable event under a different jurisdiction's laws): (a) if any asset, right, obligation or liability of any Person becomes the asset, right, obligation or liability of a different Person, then it shall be deemed to have been transferred from the original Person to the subsequent Person and (b) if any new Person comes into existence, such new Person shall be deemed to have been organized on the first date of its existence by the holders of its Equity Interests at such time.

1.3 If at any time any change in GAAP would affect the computation of any financial requirement set forth in any Loan Document, and either the Borrower or the Required Lenders shall so request, Agent, Lenders and the Borrower shall negotiate in good faith to amend such requirement to preserve the original intent thereof in light of such change in GAAP; provided that, until so amended, such requirement shall continue to be computed in accordance with GAAP prior to such change.

SECTION 2. THE LOAN

1.4 Term Loan Advances.

(a) Term Commitment.

(i) *Tranche I.* Subject to the terms and conditions of this Agreement, (A) on the Closing Date, Lenders shall severally (and not jointly) make, and Borrower agrees to draw, a Term Loan Advance in an amount equal to Ten Million Dollars ($10,000,000) in accordance with their respective Tranche I Commitments, and (B) at any time from the Closing Date until June 15, 2023, Borrower may request and Lenders shall severally (and not jointly) make one or more additional Term Loan Advances in minimum increments of Five Million Dollars ($5,000,000) (or if less, the remaining amount of Term Loan Advances available to be drawn pursuant to this Section 2.1(a)(i)(B)) in an aggregate principal amount up to Ten Million Dollars ($10,000,000) in accordance with their respective Tranche I Commitments (such Term Loan Advances, the "Tranche I Advances"). After repayment, no Tranche I Advance (or any portion thereof) may be reborrowed.

(ii) *Tranche II.* Subject to the terms and conditions of this Agreement, at any time on or after the Tranche II Milestone Date until December 15, 2023, Borrower may request, and Lenders shall severally (and not jointly) make, one or more additional Term Loan Advances in minimum increments of Five Million Dollars ($5,000,000) (or if less, the remaining amount of Term Loan Advances available to be drawn pursuant to this Section 2.1(a)(ii)) in an aggregate principal amount up to Fifteen Million Dollars ($15,000,000) in accordance with their respective Tranche II Commitments (such Term Loan Advances, the "Tranche II Advances"). After repayment, no Tranche II Advance (or any portion thereof) may be reborrowed.

(iii) *Tranche III.* Subject to the terms and conditions of this Agreement, at any time on or after the Tranche III Milestone Date until March 15, 2024, Borrower may request, and Lenders shall severally (and not jointly) make, one or more additional Term Loan Advances in minimum increments of Five Million Dollars ($5,000,000) (or if less, the remaining amount of Term Loan Advances available to be drawn pursuant to this Section 2.1(a)(iii)) in an aggregate principal amount up to Twenty Million Dollars ($20,000,000) in accordance with their respective Tranche III Commitments (such Term Loan Advances, the "Tranche III Advances"). After repayment, no Tranche III Advance (or any portion thereof) may be reborrowed.

(iv) *Tranche IV.* Subject to the terms and conditions of this Agreement and conditioned on approval by the Lenders' investment committee in its sole and unfettered discretion, prior to September 15, 2024, Borrower may request, and Lenders shall severally (and not jointly) make, one or more additional Term Loan Advances in minimum increments of Five Million Dollars ($5,000,000) (or if less, the remaining amount of Term

Loan Advances available to be drawn pursuant to this Section 2.1(a)(iv)) in an aggregate principal amount up to Forty-Five Million Dollars ($45,000,000) in accordance with their respective Tranche IV Commitments, to be used, among other things, to fund the pipeline expansion and strategic business development efforts of Borrower (such Term Loan Advances, the "Tranche IV Advances"). After repayment, no Tranche IV Advance (or any portion thereof) may be reborrowed.

(a) Maximum Term Loan Amount. The aggregate outstanding Term Loan Advances may be up to the Maximum Term Loan Amount.

(b) Advance Request. To obtain a Term Loan Advance, Borrower shall complete, sign and deliver an Advance Request (at least one (1) Business Day before the Closing Date and at least five (5) Business Days before each Advance Date other than the Closing Date) to Agent. The Lenders shall fund the Term Loan Advance in the manner requested by the Advance Request provided that each of the conditions precedent set forth in Section 4 and applicable to such Term Loan Advance is satisfied as of the requested Advance Date.

(c) Term Loan Interest Rate. The principal balance shall bear interest thereon from such Advance Date at the Term Loan Interest Rate based on a year consisting of three hundred sixty (360) days, with interest computed daily based on the actual number of days elapsed. The Term Loan Interest Rate will float and change on the day the prime rate changes from time to time.

(d) Payment. Borrower will pay accrued but unpaid interest on each Term Loan Advance on the first Business Day of each month, beginning the month after the Advance Date. Borrower shall repay the aggregate Term Loan principal balance that is outstanding on the day immediately preceding the Amortization Date, in equal monthly installments of principal and interest (mortgage style) beginning on the Amortization Date and continuing on the first Business Day of each month thereafter until the Secured Obligations (other than inchoate indemnity or reimbursement obligations and any other obligations which, by their terms, are to survive the termination of this Agreement) are repaid. The entire Term Loan principal balance and all accrued but unpaid interest hereunder, shall be due and payable on the Term Loan Maturity Date. Borrower shall make all payments under this Agreement without setoff, recoupment or deduction and regardless of any counterclaim or defense. If a payment hereunder becomes due and payable on a day that is not a Business Day, the due date thereof shall be the immediately preceding Business Day. The Lenders will initiate debit entries to the Borrower's account as authorized on the ACH Authorization (i) on each payment date of all periodic obligations payable to the Lenders under each Term Loan Advance and (ii) reasonable and documented out-of-pocket legal fees and costs incurred by Agent or the Lenders in connection with Section 11.12 of this Agreement; provided that, with respect to clause (i) above, in the event that the Lenders or Agent informs Borrower that the Lenders will not initiate a debit entry to Borrower's account for a certain amount of the periodic obligations due on a specific payment date, Borrower shall pay to the Agent, for the ratable benefit of the Lenders, such amount of periodic obligations in full in immediately available funds on such payment date; provided, further, that, with respect to clause (i) above, if the Lenders or Agent informs Borrower that the Lenders will not initiate a debit entry as described above later than the date that is three (3) Business Days prior to such payment date, Borrower shall pay to the Agent, for the ratable benefit of the Lenders, such amount of periodic obligations in full in immediately available funds on the date that is three (3) Business Days after the date on which the Lenders or Agent notifies Borrower of such; provided, further, that, with respect to clause (ii) above, in the event that the Lenders or Agent informs Borrower that the Lenders will not initiate a debit entry to Borrower's account for certain amount of such out-of-pocket legal fees and costs incurred by Agent

or the Lenders, Borrower shall pay to the Lenders such amount in full in immediately available funds within three (3) Business Days.

2.2 Maximum Interest. Notwithstanding any provision in this Agreement or any other Loan Document, it is the parties' intent not to contract for, charge or receive interest at a rate that is greater than the maximum rate permissible by law that a court of competent jurisdiction shall deem applicable hereto (which under the laws of the State of California shall be deemed to be the laws relating to permissible rates of interest on commercial loans) (the "Maximum Rate"). If a court of competent jurisdiction shall finally determine that Borrower has actually paid to the Lenders an amount of interest in excess of the amount that would have been payable if all of the Secured Obligations had at all times borne interest at the Maximum Rate, then such excess interest actually paid by Borrower shall be applied as follows: first, to the payment of the Secured Obligations consisting of the outstanding principal; second, after all principal is repaid, to the payment of the Lenders' accrued interest, reasonable and documented out-of-pocket costs, expenses, professional fees and any other Secured Obligations; and third, after all Secured Obligations are repaid, the excess (if any) shall be refunded to Borrower.

2.3 Default Interest. In the event any payment is not paid on the scheduled payment date, an amount equal to five percent (5%) of such past due amount shall be payable on demand. In addition, upon the occurrence and during the continuation of an Event of Default hereunder, all outstanding Secured Obligations, including principal, interest, compounded interest, and reasonable and documented out-of-pocket professional fees, shall bear interest at a rate per annum equal to the rate set forth in Section 2.1(c) plus five percent (5%) per annum. In the event any interest is not paid when due hereunder, delinquent interest shall be added to principal and shall bear interest on interest, compounded at the rate set forth in Section 2.1(c) or Section 2.3, as applicable.

2.4 Prepayment. At its option, Borrower may prepay all or a portion of the outstanding Advances by paying the entire principal balance, or such portion thereof, all accrued and unpaid interest thereon, all unpaid Lender's fees and expenses due hereunder accrued to the date of the repayment (including, without limitation, the portion of the End of Term Charge applicable to the aggregate original principal amount of the Term Loan Advances being prepaid in accordance with Section 2.5(a)), together with a prepayment charge equal to the following percentage of the outstanding principal amount of such Advance amount being so prepaid: with respect to each Advance (a) if the principal amount of such Advance amounts are prepaid on or prior to the date which is twelve (12) months following the Closing Date, three percent (3.00%); (b) if the principal amount of such Advance amounts are prepaid after the date which is twelve (12) months following the Closing Date but on or prior to the date which is twenty-four (24) months following the Closing Date, two percent (2.00%); and (c) thereafter through the day before the Term Loan Maturity Date, one percent (1.00%) (each, a "Prepayment Charge"). Borrower agrees that the Prepayment Charge is a reasonable calculation of the Lenders' lost profits in view of the difficulties and impracticality of determining actual damages resulting from an early repayment of the Advances. Borrower shall prepay the outstanding amount of all principal and accrued interest through the prepayment date and the Prepayment Charge upon the occurrence of a Change in Control or any other prepayment hereunder. Notwithstanding the foregoing, Agent and the Lenders agree to waive the Prepayment Charge if Agent and the Lenders (in their sole and absolute discretion) agree in writing to refinance the Advances prior to the Term Loan Maturity Date. Any amounts paid under this Section shall be applied by Agent to the then unpaid amount of any outstanding Secured Obligations (including principal and interest) in such order and priority as Agent may choose in its sole discretion. For the avoidance of doubt, if a payment hereunder becomes due and payable on a day that is not a Business Day, the due date thereof shall be the immediately preceding Business Day.

2.5 End of Term Charge.

(a) On any date that Borrower partially prepays the outstanding Secured Obligations pursuant to Section 2.4, Borrower shall pay the Lenders a charge of five and seventeen-twentieths of one percent (5.85%) multiplied by the principal amount of such Term Loan Advances being prepaid.

(b) On the earliest to occur of (i) the Term Loan Maturity Date, (ii) the date that Borrower prepays the outstanding Secured Obligations (other than any inchoate indemnity or reimbursement obligations and any other obligations which, by their terms, are to survive the termination of this Agreement) in full, or (iii) the date that the outstanding Secured Obligations become due and payable, Borrower shall pay the Lenders a charge equal to (x) the greater of (I) One Million One Hundred Seventy Thousand Dollars ($1,170,000) and (II) five and seventeen-twentieths of one percent (5.85%) multiplied by the aggregate original principal amount of the Term Loan Advances made hereunder, whichever is higher, *minus* (y) the aggregate amount of payments made pursuant to Section 2.5(a) (the "End of Term Charge").

(c) Notwithstanding the required payment date of such End of Term Charge, the applicable pro rata portion of the End of Term Charge calculated pursuant to the preceding sentence shall be deemed earned by the Lenders as of each date that an applicable Term Loan Advance is made. For the avoidance of doubt, if a payment hereunder becomes due and payable on a day that is not a Business Day, the due date thereof shall be the immediately preceding Business Day.

2.6 Pro Rata Treatment. Each payment (including prepayment) on account of any fee and any reduction of the Term Loan Advances shall be made pro rata according to the Term Commitments of the relevant Lender.

2.7 Taxes; Increased Costs. The Borrower, the Agent and the Lenders each hereby agree to the terms and conditions set forth on Addendum 1 attached hereto.

2.8 Treatment of Prepayment Charge and End of Term Charge. Borrower agrees that any Prepayment Charge and any End of Term Charge payable shall be presumed to be the liquidated damages sustained by each Lender as the result of the early termination, and Borrower agrees that it is reasonable under the circumstances currently existing and existing as of the Closing Date. The Prepayment Charge and the End of Term Charge shall also be payable in the event the Secured Obligations (and/or this Agreement) are satisfied or released by foreclosure (whether by power of judicial proceeding), deed in lieu of foreclosure, or by any other means. Borrower expressly waives (to the fullest extent it may lawfully do so) the provisions of any present or future statute or law that prohibits or may prohibit the collection of the foregoing Prepayment Charge and End of Term Charge in connection with any such acceleration. Borrower agrees (to the fullest extent that each may lawfully do so): (a) each of the Prepayment Charge and the End of Term Charge is reasonable and is the product of an arm's length transaction between sophisticated business people, ably represented by counsel; (b) each of the Prepayment Charge and the End of Term Charge shall be payable notwithstanding the then prevailing market rates at the time payment is made; (c) there has been a course of conduct between the Lenders and Borrower giving specific consideration in this transaction for such agreement to pay the Prepayment Charge and the End of Term Charge as a charge (and not interest) in the event of prepayment or acceleration; and (d) Borrower shall be estopped from claiming differently than as agreed to in this paragraph. Borrower expressly acknowledges that its agreement to pay each of the Prepayment Charge and the End of Term Charge

to the Lenders as herein described was on the Closing Date and continues to be a material inducement to the Lenders to provide the Term Loan Advances.

SECTION 3. SECURITY INTEREST

3.1 As security for the prompt and complete payment when due (whether on the payment dates or otherwise) of all the Secured Obligations, Borrower grants to Agent a security interest in all of Borrower's right, title, and interest in, to and under all of Borrower's personal property and other assets including without limitation the following (except as set forth herein) whether now owned or hereafter acquired (collectively, the "Collateral"): (a) Receivables; (b) Equipment; (c) Fixtures; (d) General Intangibles (other than Intellectual Property); (e) Inventory; (f) Investment Property; (g) Deposit Accounts; (h) Cash; (i) Goods; and all other tangible and intangible personal property of Borrower whether now or hereafter owned or existing, leased, consigned by or to, or acquired by, Borrower and wherever located, and any of Borrower's property in the possession or under the control of Agent; and, to the extent not otherwise included, all Proceeds of each of the foregoing and all accessions to, substitutions and replacements for, and rents, profits and products of each of the foregoing; provided, however, that the Collateral shall include all Accounts and General Intangibles that consist of rights to payment and proceeds from the sale, licensing or disposition of all or any part, or rights in, the Intellectual Property (the "Rights to Payment"). Notwithstanding the foregoing, if a judicial authority (including a U.S. Bankruptcy Court) holds that a security interest in the underlying Intellectual Property is necessary to have a security interest in the Rights to Payment, then the Collateral shall automatically, and effective as of the date of this Agreement, include the Intellectual Property to the extent necessary to permit perfection of Agent's security interest in the Rights to Payment.

3.2 Notwithstanding the broad grant of the security interest set forth in Section 3.1, above, the Collateral shall not include (a) nonassignable licenses or contracts, which by their terms require the consent of the licensor thereof or another party (but only to the extent such prohibition on transfer is enforceable under applicable law, including, without limitation, Sections 9406, 9407 and 9408 of the UCC), provided further, that upon the termination of such prohibition or such consent being provided with respect to any license or contract, such license or contract shall automatically be included in the Collateral; (b) any lease, license or other agreement and any property subject thereto on the Closing Date or on the date of the acquisition of such property (other than any property acquired by Borrower subject to any such contract or other agreement to the extent such contract or other agreement was incurred in contemplation of such acquisition) to the extent that a grant of a security interest therein to secure the Secured Obligations would violate or invalidate such lease, license, contract or agreement or create a right of termination in favor of any other party thereto (other than the Borrower or any Subsidiary) (but (A) only to the extent such prohibition is enforceable under applicable law, rule or regulation, and (B) other than to the extent that any such term would be rendered ineffective pursuant to Sections 9-406, 9-408 or 9-409 (or any other Section) of Article 9 of the UCC); (c) any cash collateral deposit subject to a Permitted Lien hereunder, if the grant of a security interest with respect to such property pursuant to this Agreement would be prohibited by the agreement creating such Permitted Lien or would otherwise constitute a default thereunder or create a right of termination a party thereto (other than Borrower), provided that upon the termination and release of such cash collateral, such property shall automatically be included in the Collateral; (d) any trademark application filed on an "intent-to-use" basis until the earlier of the filing of a statement of use with respect thereto or the issuance of a registration therefor, (e) any Excluded Account, (f) assets as to Agent and Borrower agrees that the costs of obtaining or perfecting such security interest are excessive in relation to the benefit to the Lenders of the security to be afforded thereby, and (g) more than 65% of the presently existing and hereafter arising issued

and outstanding Equity Interests owned by Borrower of any Foreign Subsidiary or FSHCO which Equity Interests entitle the holder thereof to vote for directors or any other matter.

3.3 The security interest granted in Section 3.1 shall continue until the Secured Obligations (other than any inchoate indemnity or reimbursement obligations and any other obligations which, by their terms, are to survive the termination of this Agreement) have been paid in full and Agent has no further commitment or obligation hereunder or under the other Loan Documents to make any further Advances, and shall thereupon terminate, and Lender shall, at Borrower's expense, take all actions reasonably requested by Borrower to evidence such termination.

SECTION 4. CONDITIONS PRECEDENT TO LOAN

The obligations of the Lenders to make the Loan hereunder are subject to the satisfaction by Borrower of the following conditions:

4.1 Initial Advance. On or prior to the Closing Date, Borrower shall have delivered to Agent the following:

(a) executed copies of the Loan Documents (other than the Warrant, which shall be an original), and all other documents and instruments reasonably required by Agent to effectuate the transactions contemplated hereby or to create and perfect the Liens of Agent with respect to all Collateral, in all cases in form and substance reasonably acceptable to Agent;

(b) duly executed Account Control Agreement(s) with respect to each Deposit Account and account holding Investment Property (other than an Excluded Account) maintained by Borrower or any Subsidiary (other than the MSC Subsidiary);

(c) a legal opinion of Borrower's counsel in form and substance reasonably acceptable to Agent;

(d) a copy of resolutions of Borrower's Board of Directors evidencing approval of the Loan and other transactions evidenced by the Loan Documents (including the Warrant), certified by an officer of Borrower;

(e) certified copies of the Certificate of Incorporation and the Bylaws, as amended through the Closing Date, of Borrower;

(f) a certificate of good standing for Borrower from its state of incorporation and similar certificates from all other jurisdictions in which it does business and where the failure to be qualified would have a Material Adverse Effect;

(g) any required filing in the central filing office of the State of Delaware, accompanied by written evidence (including any UCC termination statements) that the Liens on any Collateral indicated in any such financing statements either constitute Permitted Liens or have been or, in connection with the initial Term Loan Advance, will be terminated or released;

(h) payment of the Due Diligence Fee (to the extent not already paid), Initial Facility Charge and reimbursement of Agent's and the Lenders' current reasonable, documented, and

out-of-pocket expenses reimbursable pursuant to this Agreement, which amounts may be deducted from the initial Advance;

(i) all certificates of insurance required hereunder;

(j) duly executed landlord's consent(s) in favor of Agent for each of Borrower's leased locations (other than Borrower's headquarters location) at which Collateral with a value in excess of Three Hundred Thousand Dollars ($300,000) is located;

(k) duly executed bailee's waiver(s) in favor of Agent for each location (other than Borrower's headquarters location) where Borrower maintains property with a third party and at which Collateral with a value in excess of Three Hundred Thousand Dollars ($300,000) is located;

(l) a duly executed copy of the Perfection Certificate and each exhibit and addendum thereto; and

(m) such other documents as Agent may have reasonably requested.

4.2 All Advances. On each Advance Date:

(a) Agent shall have received (i) an Advance Request for the relevant Advance as required by Section 2.1(c), each duly executed by Borrower's Chief Executive Officer or Chief Operating Officer, and (ii) any other documents Agent may reasonably request.

(b) The representations and warranties set forth in this Agreement shall be true and correct in all material respects on and as of the applicable Advance Date with the same effect as though made on and as of such date, except to the extent such representations and warranties expressly relate to an earlier date.

(c) Borrower shall be in compliance with all the terms and provisions set forth herein and in each other Loan Document on its part to be observed or performed, and at the time of and immediately after such Advance no Event of Default shall have occurred and be continuing.

(d) With respect to any Advance (other than the Tranche I Advance) made available on such Advance Date, Borrower shall have paid the Facility Charge applicable to such Advance;

(e) Each Advance Request shall be deemed to constitute a representation and warranty by Borrower on the relevant Advance Date as to the matters specified in subsections (b) and (c) of this Section 4.2 and as to the matters set forth in the Advance Request.

4.3 No Default. As of the Closing Date and each Advance Date, (i) no fact or condition exists that could (or could, with the passage of time, the giving of notice, or both) constitute an Event of Default and (ii) no event that has had or could reasonably be expected to have a Material Adverse Effect has occurred and is continuing.

SECTION 5. REPRESENTATIONS AND WARRANTIES OF BORROWER

Borrower represents and warrants that:

5.1 Corporate Status. Borrower is a corporation duly organized, legally existing and in good standing under the laws its state of formation, and is duly qualified as a foreign corporation, limited liability company or partnership, as the case may be, in all jurisdictions in which the nature of its business or location of its properties require such qualifications and where the failure to be qualified could reasonably be expected to have a Material Adverse Effect. Borrower's present name, former names (if any), locations, place of formation, tax identification number, organizational identification number and other information are correctly set forth in Exhibit B, as may be updated by Borrower in a written notice (including any Compliance Certificate) provided to Agent after the Closing Date in accordance with this Agreement.

5.2 Collateral. Borrower owns or otherwise has the rights to use the Collateral and owns, or has rights to, the Intellectual Property, free of all Liens, except for Permitted Liens. Borrower has the power and authority to grant to Agent a Lien in the Collateral as security for the Secured Obligations.

5.3 Consents. Borrower's execution, delivery and performance of this Agreement and all other Loan Documents, and Borrower's execution of the Warrant, (i) have been duly authorized by all necessary corporate action of Borrower, (ii) will not result in the creation or imposition of any Lien upon the Collateral, other than Permitted Liens and the Liens created by this Agreement and the other Loan Documents, (iii) do not violate any provisions of Borrower's Certificate or Articles of Incorporation (as applicable), bylaws, or any, law, regulation, order, injunction, judgment, decree or writ to which Borrower is subject and (iv) except as described on Schedule 5.3, do not violate any material contract or agreement or require the consent or approval of any other Person which has not already been obtained. The individual or individuals executing the Loan Documents and the Warrant are duly authorized to do so.

5.4 Material Adverse Effect. No event that has had or could reasonably be expected to have a Material Adverse Effect has occurred and is continuing. Borrower is not aware of any event likely to occur that is reasonably expected to result in a Material Adverse Effect.

5.5 Actions Before Governmental Authorities. There are no actions, suits or proceedings at law or in equity or by or before any governmental authority now pending or, to the knowledge of Borrower, threatened against or affecting Borrower or its property, that is reasonably expected to result in a Material Adverse Effect.

5.6 Laws.

(a) Neither Borrower nor any of its Subsidiaries is in violation of any law, rule or regulation, or in default with respect to any judgment, writ, injunction or decree of any governmental authority to which Borrower or such Subsidiaries are subject, where such violation or default could reasonably be expected to result in a Material Adverse Effect. Borrower is not in default in any manner under any provision of any agreement or instrument evidencing material Indebtedness, or any other material agreement to which it is a party or by which it is bound.

(b) Neither Borrower nor any of its Subsidiaries is an "investment company" or a company "controlled" by an "investment company" under the Investment Company Act of 1940, as amended. Neither Borrower nor any of its Subsidiaries is engaged as one of its important activities in extending credit for margin stock (under Regulations X, T and U of the Federal Reserve Board of Governors). Borrower and each of its Subsidiaries has complied in all material respects with the Federal Fair Labor Standards Act. Neither Borrower nor any of its Subsidiaries is a

"holding company" or an "affiliate" of a "holding company" or a "subsidiary company" of a "holding company" as each term is defined and used in the Public Utility Holding Company Act of 2005. Neither Borrower's nor any of its Subsidiaries' properties or assets have been used by Borrower or such Subsidiary or, to Borrower's knowledge, by previous Persons, in disposing, producing, storing, treating, or transporting any hazardous substance other than in material compliance with applicable laws. Borrower and each of its Subsidiaries has obtained all consents, approvals and authorizations of, made all declarations or filings with, and given all notices to, all governmental authorities that are necessary to continue their respective businesses as currently conducted.

(c) None of Borrower, any of its Subsidiaries, or any of Borrower's or its Subsidiaries' Affiliates or any of their respective agents acting or benefiting in any capacity in connection with the transactions contemplated by this Agreement is (i) in violation of any Anti-Terrorism Law, (ii) engaging in or conspiring to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding or attempts to violate, any of the prohibitions set forth in any Anti-Terrorism Law, or (iii) is a Blocked Person. None of Borrower, any of its Subsidiaries, or to the knowledge of Borrower and any of their Affiliates or agents, acting or benefiting in any capacity in connection with the transactions contemplated by this Agreement, (x) conducts any business or engages in making or receiving any contribution of funds, goods or services to or for the benefit of any Blocked Person, or (y) deals in, or otherwise engages in any transaction relating to, any property or interest in property blocked pursuant to Executive Order No. 13224, any similar executive order or other Anti-Terrorism Law. None of the funds to be provided under this Agreement shall be used, directly or indirectly, (a) for any activities in violation of any applicable anti-money laundering, economic sanctions and anti-bribery laws and regulations or (b) for any payment to any governmental official or employee, political party, official of a political party, candidate for political office, or anyone else acting in an official capacity, in order to obtain, retain or direct business or obtain any improper advantage, in violation of the United States Foreign Corrupt Practices Act of 1977, as amended.

5.7 Information Correct and Current. No information, report, Advance Request, financial statement, exhibit or schedule furnished, by or on behalf of Borrower to Agent in connection with any Loan Document or included therein or delivered pursuant thereto (other than financial or business projections) contained, or, when taken as a whole, contains or will contain any material misstatement of fact or, when taken together with all other such information or documents, omitted, omits or will omit to state any material fact necessary to make the statements therein, in the light of the circumstances under which they were, are or will be made, not materially misleading at the time such statement was made or deemed made. Additionally, any and all financial or business projections provided by Borrower to Agent, whether prior to or after the Closing Date, shall be (i) provided in good faith and based on the most current data and information available to Borrower, and (ii) the most current of such projections provided to Borrower's Board of Directors, provided that it is understood that the projections are based on assumptions made in good faith but are subject to significant uncertainties and contingencies, many of which are beyond the control of Borrower, and that actual results may differ significantly and no assurances are provided by Borrower for any projections made or given.

5.8 Tax Matters. Except as set forth on Schedule 5.8, (a) Borrower and its Subsidiaries have filed all federal and state income Tax returns and other material Tax returns that they are required to file (taking into account any timely filed extensions), (b) Borrower and its Subsidiaries have duly paid all federal and state income Taxes and other material Taxes or installments thereof that they are required to pay, except Taxes being contested in good faith by appropriate proceedings and for which Borrower and its Subsidiaries maintain adequate reserves in accordance with GAAP

or such Taxes that do not, individually or in the aggregate, exceed Fifty Thousand Dollars ($50,000), and (c) to Borrower's knowledge, no proposed or pending Tax assessments, deficiencies, audits or other proceedings with respect to Borrower or any Subsidiary have had, or could reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect.

5.9 Intellectual Property Claims. Borrower is the sole owner of, or otherwise has the right to use, the Intellectual Property material to Borrower's business. Except as described on Schedule 5.9, (i) each of the material Copyrights, Trademarks and Patents is valid and enforceable, (ii) no material part of the Intellectual Property has been judged invalid or unenforceable, in whole or in part, and (iii) no claim has been made to Borrower that any material part of the Intellectual Property violates the rights of any third party. Exhibit C is a true, correct and complete list of each of Borrower's Patents, registered Trademarks, registered Copyrights, and material agreements under which Borrower licenses Intellectual Property from third parties (other than shrink-wrap software licenses or other than "off-the-shelf" licenses or open-source software), together with application or registration numbers, as applicable, owned by Borrower or any Subsidiary, in each case as of the Closing Date. Borrower is not in material breach of, nor has Borrower failed to perform any material obligations under, any of the foregoing contracts, licenses or agreements and, to Borrower's knowledge, no third party to any such contract, license or agreement is in material breach thereof or has failed to perform any material obligations thereunder.

5.10 Intellectual Property.

(a) Except as described on Schedule 5.10, Borrower has all material rights with respect to Intellectual Property necessary or material in the operation or conduct of Borrower's business as currently conducted and proposed to be conducted by Borrower. Without limiting the generality of the foregoing, and in the case of Licenses, except for restrictions that are unenforceable under Division 9 of the UCC or otherwise permitted under this Agreement, Borrower has the right, to the extent required to operate Borrower's business, to freely transfer, license or assign Intellectual Property necessary or material in the operation or conduct of Borrower's business as currently conducted and proposed to be conducted by Borrower, without condition, restriction or payment of any kind (other than license payments in the ordinary course of business) to any third party, and Borrower owns or has the right to use, pursuant to valid licenses, all software development tools, library functions, compilers and all other third-party software and other items that are material in the operation or conduct of Borrower's business and used in the design, development, promotion, sale, license, manufacture, import, export, use or distribution of Borrower Products except customary covenants in inbound license agreements and equipment leases where Borrower is the licensee or lessee. Except as disclosed on Schedule 5.10, Borrower is not a party to, nor is it bound by, any Restricted License.

(b) No material software or other materials used by Borrower or any of its Subsidiaries (or used in any Borrower Products or any Subsidiaries' products) are subject to an open-source or similar license (including but not limited to the General Public License, Lesser General Public License, Mozilla Public License, or Affero License) in a manner that would cause such software or other materials to have to be (i) distributed to third parties at no charge or a minimal charge (royalty-free basis); (ii) licensed to third parties to modify, make derivative works based on, decompile, disassemble, or reverse engineer; or (iii) used in a manner that requires disclosure or distribution in source code form.

5.11 Borrower Products. Except as described on Schedule 5.11, no Intellectual Property owned by Borrower or Borrower Product has been or is subject to any actual or, to the knowledge

of Borrower, threatened litigation, proceeding (including any proceeding in the United States Patent and Trademark Office or any corresponding foreign office or agency, except for routine prosecution of such Intellectual Property in the United States Patent and Trademark Office or any corresponding foreign office or agency) or outstanding decree, order, judgment, settlement agreement or stipulation that restricts in any material manner Borrower's use, transfer or licensing thereof or that could reasonably be expected to adversely affect the validity, use or enforceability thereof. There is no decree, order, judgment, agreement, stipulation, arbitral award or other provision entered into in connection with any litigation or proceeding that obligates Borrower to grant licenses or ownership interest in any future material Intellectual Property related to the operation or conduct of the business of Borrower or Borrower Products. Borrower has not received any written notice or claim, or, to the knowledge of Borrower, oral notice or claim, challenging or questioning Borrower's ownership in any Intellectual Property material to the operation or conduct of the business of Borrower (or written notice of any claim challenging or questioning the ownership in any licensed Intellectual Property of the owner thereof) or suggesting that any third party has any claim of legal or beneficial ownership with respect thereto nor, to Borrower's knowledge, is there a reasonable basis for any such claim. Neither Borrower's use of its Intellectual Property nor the production and sale of Borrower Products infringes the Intellectual Property or other rights of others.

5.12 Financial Accounts. Exhibit D, as may be updated by the Borrower in a written notice provided to Agent after the Closing Date, is a true, correct and complete list of (a) all banks and other financial institutions at which Borrower or any Subsidiary maintains Deposit Accounts and (b) all institutions at which Borrower or any Subsidiary maintains an account holding Investment Property, and such exhibit correctly identifies the name, address and telephone number of each bank or other institution, the name in which the account is held, a description of the purpose of the account, and the complete account number therefor.

5.13 Employee Loans. Except for loans constituting Permitted Investments or as described on Schedule 5.13, Borrower has no outstanding loans to any employee, officer or director of the Borrower nor has Borrower guaranteed the payment of any loan made to an employee, officer or director of the Borrower by a third party.

5.14 Capitalization and Subsidiaries. Borrower's capitalization as of the Closing Date is set forth on Schedule 5.14 annexed hereto. Borrower does not own any stock, partnership interest or other securities of any Person, except for Permitted Investments. Attached as Schedule 5.14, as may be updated by Borrower in a written notice provided after the Closing Date, is a true, correct and complete list of each Subsidiary.

SECTION 6. INSURANCE; INDEMNIFICATION

6.1 Coverage. Borrower shall cause to be carried and maintained commercial general liability insurance, on an occurrence form, against risks customarily insured against by businesses of Borrower's size in Borrower's line of business in similar locations. Such risks shall include the risks of bodily injury, including death, property damage, personal injury, advertising injury, and contractual liability per the terms of the indemnification agreement found in Section 6.3. Borrower must maintain a minimum of One Million Dollars ($1,000,000) of commercial general liability insurance for each occurrence. Borrower has and agrees to maintain a minimum of One Million Dollars ($1,000,000) of directors' and officers' insurance for each occurrence and Four Million Dollars ($4,000,000) in the aggregate. So long as there are any Secured Obligations outstanding (other than inchoate indemnification or reimbursement obligations or other obligations which, by their terms, survive termination of this Agreement), Borrower shall also cause to be carried and

maintained insurance upon the Collateral, insuring against all risks of physical loss or damage howsoever caused, in an amount not less than the full replacement cost of the Collateral, provided that such insurance may be subject to standard exceptions and deductibles. If Borrower fails to obtain the insurance called for by this Section 6.1 or fails to pay any premium thereon or fails to pay any other amount which Borrower is obligated to pay under this Agreement or any other Loan Document or which may be required to preserve the Collateral, Agent may obtain such insurance or make such payment, and all amounts so paid by Agent are immediately due and payable, bearing interest at the then highest rate applicable to the Secured Obligations, and secured by the Collateral. Agent will make reasonable efforts to provide Borrower with notice of Agent obtaining such insurance at the time it is obtained or within a reasonable time thereafter. No payments by Agent are deemed an agreement to make similar payments in the future or Agent's waiver of any Event of Default.

Notwithstanding anything to the contrary contained in this Section 6.1, so long as no Event of Default has occurred and is continuing, Borrower may elect to use up to Two Million Dollars ($2,000,000) in the aggregate in any fiscal year of the proceeds of any casualty policy with respect to any losses (i) within one hundred eighty (180) days of the receipt of such proceeds, toward the repair or replacement of the property that was subject to the casualty, or (ii) as a prepayment of the outstanding amount of all principal of and accrued interest on loan amounts outstanding under this Agreement.

6.2 Certificates. Borrower shall deliver to Agent certificates of insurance that evidence Borrower's compliance with its insurance obligations in Section 6.1 and the obligations contained in this Section 6.2. Borrower's insurance certificate shall state Agent (shown as "Hercules Capital, Inc., as Agent") is an additional insured for commercial general liability, a lenders loss payable for all risk property damage insurance, subject to the insurer's approval, and a lenders loss payable for property insurance and additional insured for liability insurance for any future insurance that Borrower may acquire from such insurer. Attached to the certificates of insurance will be additional insured endorsements for liability and lender's loss payable endorsements for all risk property damage insurance. All certificates of insurance will provide for a minimum of thirty (30) days advance written notice to Agent of cancellation (other than cancellation for non-payment of premiums, for which ten (10) days' advance written notice shall be sufficient). Any failure of Agent to scrutinize such insurance certificates for compliance is not a waiver of any of Agent's rights, all of which are reserved. Borrower shall provide Agent with copies of each insurance policy, and upon entering or amending any insurance policy required hereunder, Borrower shall provide Agent with copies of such policies and shall promptly deliver to Agent updated insurance certificates with respect to such policies.

6.3 Indemnity. Borrower agrees to indemnify and hold Agent, the Lenders and their officers, directors, employees, agents, in-house attorneys, representatives and shareholders (each, an "Indemnified Person") harmless from and against any and all third-party claims, reasonable and documented out-of-pocket costs, expenses, damages and liabilities (including such claims, costs, expenses, damages and liabilities based on liability in tort, including strict liability in tort), including reasonable and documented out-of-pocket attorneys' fees and disbursements and other costs of investigation or defense (including those incurred upon any appeal) (collectively, "Liabilities"), that may be instituted or asserted against or incurred by such Indemnified Person as the result of credit having been extended, suspended or terminated under this Agreement and the other Loan Documents or the administration of such credit, or in connection with or arising out of the transactions contemplated hereunder and thereunder, or any actions or failures to act in connection therewith, or arising out of the disposition or utilization of the Collateral, excluding in all cases Liabilities to the

extent such Liabilities arise solely out of gross negligence or willful misconduct of any Indemnified Person or changes in income tax rates. This Section 6.3 shall not apply with respect to Taxes other than any Taxes that represent losses, claims, damages, etc. arising from any non-Tax claim. In no event shall any Indemnified Person be liable on any theory of liability for any special, indirect, consequential or punitive damages (including any loss of profits, business or anticipated savings). This Section 6.3 shall survive the repayment of indebtedness under, and otherwise shall survive the expiration or other termination of, this Agreement.

SECTION 7. COVENANTS OF BORROWER

Borrower agrees as follows:

7.1 Financial Reports. Borrower shall furnish to Agent the financial statements and reports listed hereinafter (the "Financial Statements"):

(a) as soon as practicable (and in any event within thirty (30) days) after the end of each month, unaudited interim and year-to-date financial statements as of the end of such month (prepared on a consolidated and consolidating basis, if applicable), including balance sheet and related statements of income and cash flows accompanied by a report detailing any material contingencies (including the commencement of any material litigation by or against Borrower) or any other occurrence that could reasonably be expected to have a Material Adverse Effect;

(b) as soon as practicable (and in any event within forty-five (45) days after the end of each calendar quarter), unaudited interim and year-to-date financial statements as of the end of such calendar quarter (prepared on a consolidated basis, if applicable), including balance sheet and related statements of income and cash flows accompanied by a report detailing any material contingencies (including the commencement of any material litigation by or against Borrower) or any other occurrence that would reasonably be expected to have a Material Adverse Effect, certified by Borrower's Chief Executive Officer or Chief Operating Officer to the effect that they have been prepared in accordance with GAAP, except (i) for the absence of footnotes, and (ii) that they are subject to normal year-end adjustments, as well as the most recent capitalization table for Borrower;

(c) as soon as practicable (and in any event within ninety (90) days) after the end of each fiscal year, unqualified audited financial statements as of the end of such year (prepared on a consolidated and consolidating basis, if applicable), including balance sheet and related statements of income and cash flows, and setting forth in comparative form the corresponding figures for the preceding fiscal year, certified by a firm of independent certified public accountants selected by Borrower and reasonably acceptable to Agent, accompanied by any management report from such accountants;

(d) as soon as practicable (and in any event within thirty (30) days) after the end of each month, a Compliance Certificate in the form of Exhibit E;

(e) as soon as practicable (and in any event within thirty (30) days) after the end of each month, a report showing agings of accounts receivable and accounts payable;

(f) promptly after the sending or filing thereof, as the case may be, copies of any proxy statements, financial statements or reports that Akero Therapeutics has made generally available to holders of its common stock and copies of any regular, periodic and special reports or registration

statements that Akero Therapeutics files with the Securities and Exchange Commission or any governmental authority that may be substituted therefor, or any national securities exchange;

(g) [Reserved.]

(h) financial and business projections promptly following their approval by Akero Therapeutics' Board, and in any event, within sixty (60) days prior to the end of Borrower's fiscal year, as well as budgets, operating plans and other financial information reasonably requested by Agent;

(i) a copy of Borrower's 409A valuation report, if any, as soon as practicable (and in any event, within ten (10) days after such report becomes available to Borrower);

(j) insurance renewal statements, annually or otherwise promptly upon renewal of insurance policies required to be maintained in accordance with Section 6.1; and

(k) prompt (but in any event no more than three (3) Business days) notice if Borrower or any Subsidiary has knowledge that Borrower, or any Subsidiary or Affiliate of Borrower, is listed on the OFAC Lists or (a) is convicted on, (b) pleads *nolo contendere* to, (c) is indicted on, or (d) is arraigned and held over on charges involving money laundering or predicate crimes to money laundering.

Borrower shall not make any change in its (a) accounting policies or reporting practices, except as required by GAAP or (b) fiscal years or fiscal quarters. The fiscal year of Borrower shall end on December 31.

The executed Compliance Certificate and all Financial Statements required to be delivered hereunder shall be sent via e-mail to financialstatements@htgc.com with a copy to legal@htgc.com, cbarnes@htgc.com, hbhalla@htgc.com and bgironda@htgc.com provided, that if e-mail is not available or sending such Financial Statements via e-mail is not possible, they shall be faxed to Agent at: (650) 473-9194, attention Account Manager: Akero Therapeutics, Inc.

Notwithstanding the foregoing, documents required to be delivered under Sections 7.1(a), (b), (c) or (f) (to the extent any such documents are included in materials otherwise filed with the SEC) may be delivered electronically and if so delivered, shall be deemed to have been delivered on the date on which Borrower emails a link thereto to Agent; provided that Borrower shall directly provide Agent all Financial Statements required to be delivered pursuant to Section 7.1(b) and (c) hereunder.

7.2 Management Rights. Borrower shall permit any representative that Agent or the Lenders authorizes, including its attorneys and accountants, to inspect the Collateral and examine and make copies and abstracts of the books of account and records of Borrower at reasonable times and upon reasonable notice during normal business hours; provided, however, that so long as no Event of Default has occurred and is continuing, such examinations shall be limited to no more often than once per fiscal year. In addition, in connection with such inspections, any such representative shall have the right to meet with management and officers of Borrower to discuss such books of account and records. In addition, Agent or the Lenders shall be entitled at reasonable times and intervals and upon reasonable prior written notice to consult with and advise the management and officers of Borrower concerning significant business issues affecting Borrower. Such consultations shall not unreasonably interfere with Borrower's business operations. The parties intend that the rights granted Agent and the Lenders shall constitute "management rights" within the meaning of 29 C.F.R. Section 2510.3-101(d)(3)(ii), but that any advice, recommendations or participation by

Agent or the Lenders with respect to any business issues shall not be deemed to give Agent or the Lenders, nor be deemed an exercise by Agent or the Lenders of, control over Borrower's management or policies.

7.3 Further Assurances. Borrower shall from time to time execute, deliver and file, alone or with Agent, any financing statements, security agreements, collateral assignments, notices, control agreements, promissory notes or other documents to perfect, give the highest priority to Agent's Lien on the Collateral (subject to Permitted Liens) or otherwise evidence Agent's rights herein. Borrower shall from time to time procure any instruments or documents as may be reasonably requested by Agent, and take all further action that may be necessary, or that Agent may reasonably request, to perfect and protect the Liens granted hereby and thereby in accordance with the Loan Documents. In addition, and for such purposes only, Borrower hereby authorizes Agent to execute and deliver on behalf of Borrower and to file such financing statements (including an indication that the financing statement covers "all assets or all personal property" of Borrower in accordance with Section 9-504 of the UCC), collateral assignments, notices, control agreements, security agreements and other documents without the signature of Borrower either in Agent's name or in the name of Agent as agent and attorney-in-fact for Borrower. Borrower shall protect and defend Borrower's title to the Collateral and Agent's Lien thereon against all Persons claiming any interest adverse to Borrower or Agent other than Permitted Liens.

7.4 Indebtedness. Borrower shall not create, incur, assume, guarantee or be or remain liable with respect to any Indebtedness, or permit any Subsidiary so to do, other than Permitted Indebtedness, or prepay any Indebtedness or take any actions which impose on Borrower an obligation to prepay any Indebtedness, except for (a) the conversion of Indebtedness into equity securities and the payment of cash in lieu of fractional shares in connection with such conversion, (b) purchase money Indebtedness pursuant to its then applicable payment schedule, (c) prepayment by any Subsidiary of (i) inter-company Indebtedness owed by such Subsidiary to any Borrower, or (ii) if such Subsidiary is not a Borrower, intercompany Indebtedness owed by such Subsidiary to another Subsidiary that is not a Borrower, (d) payments made on Subordinated Indebtedness to the extent permitted under the relevant Subordination Agreement, or (e) as otherwise permitted hereunder or approved in writing by Agent.

7.5 Collateral. Borrower shall at all times (a) keep the Collateral, the Intellectual Property and all other property and assets used in Borrower's business or in which Borrower now or hereafter holds any interest free and clear from any legal process or Liens whatsoever (except for Permitted Liens), and (b) shall give Agent prompt written notice of any known legal process affecting the Collateral, the Intellectual Property, such other property and assets, in each case, with a value in excess of Seven Hundred Fifty Thousand Dollars ($750,000), or any Liens thereon, provided however, that the Collateral and such other property or assets may be subject to Permitted Liens except that there shall be no Liens whatsoever on Intellectual Property. Borrower shall not agree with any Person other than Agent or the Lenders not to encumber its property other than in connection with Permitted Liens. Borrower shall not enter into or suffer to exist or become effective any agreement that prohibits or limits the ability of any Borrower to create, incur, assume or suffer to exist any Lien upon any of its property (including Intellectual Property), whether now owned or hereafter acquired, to secure its obligations under the Loan Documents to which it is a party other than (i) this Agreement and the other Loan Documents, (ii) any agreements governing any purchase money Liens or capital lease obligations otherwise permitted hereby (in which case, any prohibition or limitation shall only be effective against the assets financed thereby) and (iii) customary restrictions on the assignment of leases, licenses and other agreements. Borrower shall cause its Subsidiaries to protect and defend such Subsidiary's title to its assets from and against all Persons

claiming any interest adverse to such Subsidiary, and Borrower shall cause its Subsidiaries at all times to keep such Subsidiary's property and assets free and clear from any known legal process or Liens whatsoever (except for Permitted Liens, provided however, that there shall be no Liens whatsoever on Intellectual Property), and shall give Agent prompt written notice of any legal process affecting such Subsidiary's assets, in each case, with a value in excess of Five Hundred Thousand Dollars ($500,000).

7.6 Investments. Borrower shall not directly or indirectly acquire or own, or make any Investment in or to any Person, or permit any of its Subsidiaries to do so, other than Permitted Investments.

7.7 Distributions. Borrower shall not, and shall not allow any Subsidiary to, (a) except as otherwise permitted hereunder, repurchase or redeem any class of stock or other Equity Interest other than pursuant to employee, officer, director or consultant repurchase plans, stock option plans or agreements, restricted stock agreements or other similar agreements, provided, however, in each case the repurchase or redemption price does not exceed the original consideration paid for such stock or Equity Interest, or (b) declare or pay any cash dividend or make any other cash distribution on any class of stock or other Equity Interest, except that a Subsidiary may pay dividends or make other distributions to Borrower or any Subsidiary of Borrower, (c) except for Permitted Investments, lend money to any employees, officers or directors or guarantee the payment of any such loans granted by a third party in excess of Two Hundred Fifty Thousand Dollars ($250,000) in the aggregate or (d) the conversion of any of its convertible securities into other securities pursuant to the terms of such convertible securities or otherwise in exchange thereof, or (e) waive, release or forgive any Indebtedness owed by any employees, officers or directors in excess of Two Hundred Fifty Thousand Dollars ($250,000) in the aggregate.

Notwithstanding the foregoing, and for the avoidance of doubt, this Section 7.7 shall not prohibit (i) the conversion by holders of any Permitted Convertible Debt Financing in accordance with the terms of the indenture governing such Permitted Convertible Debt Financing or the Borrower's delivery of the conversion consideration in connection therewith or the delivery of Common Stock and Cash in lieu of fractional shares of Common Stock in exchange for, or to induce the conversion of, Permitted Convertible Debt Financing; provided that the conversion consideration (or exchange or inducement consideration) paid to such holders is limited to (A) Common Stock and (B) Cash in lieu of fractional shares of Common Stock (provided further that the amount of Cash in lieu of fractional shares of Common Stock paid to holders of Permitted Convertible Debt Financing in connection with the conversion or exchange thereof, or the inducement to convert Permitted Convertible Debt Financing, shall not exceed Two Hundred Fifty Thousand Dollars ($250,000) in the aggregate in any fiscal year of the Borrower), or (ii) the making of any interest payments with respect to any Permitted Convertible Debt Financing to the extent otherwise permitted under this Agreement.

7.8 Transfers. Except for Permitted Transfers, Borrower shall not, and shall not allow any Subsidiary to, voluntarily or involuntarily transfer, sell, lease, license, lend or in any other manner convey ("Transfer") any equitable, beneficial or legal interest in any material portion of its assets (including Cash).

Notwithstanding the foregoing, and for the avoidance of doubt, this Section 7.8 shall not prohibit (i) the conversion by holders of any Permitted Convertible Debt Financing in accordance with the terms of the indenture governing such Permitted Convertible Debt Financing or the Borrower's delivery of the conversion consideration in connection therewith or the delivery of

Common Stock, and Cash in lieu of fractional shares of Common Stock in exchange for, or to induce conversions of, Permitted Convertible Debt Financing; provided that the conversion consideration (or exchange or inducement consideration) paid to such holders is limited to (A) Common Stock and (B) Cash in lieu of fractional shares of Common Stock (provided further that the amount of Cash in lieu of fractional shares of Common Stock paid to holders of Permitted Convertible Debt Financing in connection with the conversion or exchange thereof, or the inducement to convert Permitted Convertible Debt Financing, shall not exceed Two Hundred Fifty Thousand Dollars ($250,000) in the aggregate in any fiscal year of the Borrower).

7.9 Mergers and Consolidations. Borrower shall not merge or consolidate, or permit any of its Subsidiaries to merge or consolidate, with or into any other business organization (other than mergers or consolidations of (a) a Subsidiary which is not a Borrower into another Subsidiary or into Borrower or (b) a Borrower into another Borrower).

7.10 Taxes. Borrower shall, and shall cause each of its Subsidiaries to, pay when due all material Taxes of any nature whatsoever now or hereafter imposed or assessed against Borrower or such Subsidiary or the Collateral or upon Borrower's (or such Subsidiary's) ownership, possession, use, operation or disposition thereof or upon Borrower's (or such Subsidiary's) rents, receipts or earnings arising therefrom, other than such Taxes that do not, individually or in the aggregate, exceed Fifty Thousand Dollars ($50,000). Borrower shall, and shall cause each of its Subsidiaries to, accurately file on or before the due date therefor (taking into account proper extensions) all federal and state income Tax returns and other material Tax returns required to be filed. Notwithstanding the foregoing, Borrower and its Subsidiaries may contest, in good faith and by appropriate proceedings diligently conducted, Taxes for which Borrower and its Subsidiaries maintain adequate reserves in accordance with GAAP.

7.11 Corporate Changes. Neither Borrower nor any Subsidiary shall change its corporate name, legal form or jurisdiction of formation without fifteen (15) days' prior written notice to Agent. Neither Borrower nor any Subsidiary shall suffer a Change in Control. Neither Borrower nor any Subsidiary shall relocate its chief executive office or its principal place of business unless: (i) it has provided prior written notice to Agent; and (ii) such relocation shall be within the continental United States of America. Neither Borrower nor any Subsidiary shall relocate tangible items of Collateral with an aggregate value in excess of Three Hundred Thousand Dollars ($300,000) (other than (v) relocations of Collateral temporarily for sales, testing or demonstration purposes in the ordinary course of business (w) relocations of biopharmaceutical compounds and therapeutic materials in the ordinary course of business in connection with clinical trials and development arrangements, (x) sales of Inventory in the ordinary course of business, (y) relocations of mobile Equipment in the possession of Borrower's employees or agents, and (z) relocations of Collateral from a location described on Exhibit B to another location described on Exhibit B) unless (i) it has provided prompt written notice to Agent, (ii) such relocation is within the continental United States of America and, (iii) if such relocation is to a landlord or third party bailee, it has delivered a landlord waiver and consent or a bailee agreement, as the case may be, in form and substance reasonably acceptable to Agent.

7.12 Deposit Accounts. Neither Borrower nor any Subsidiary (other than the MSC Subsidiary) shall maintain any Deposit Accounts, or accounts holding Investment Property, except with respect to which Agent has an Account Control Agreement, provided that no Account Control Agreement shall be required for any Excluded Account.

7.13 Future Subsidiaries. Borrower shall notify Agent of each Subsidiary formed or acquired subsequent to the Closing Date and, within fifteen (15) days of formation, shall cause any such Subsidiary to execute and deliver to Agent a Joinder Agreement.

7.14 Notification of Event of Default. Borrower shall notify Agent promptly, and in any case within two (2) Business Days of Borrower obtaining knowledge, of the occurrence of any Event of Default.

7.15 One or more affiliates of Agent have received a license from the U.S. Small Business Administration ("SBA") to extend loans as a small business investment company ("SBIC") pursuant to the Small Business Investment Act of 1958, as amended, and the associated regulations (collectively, the "SBIC Act"). Portions of the Loan to Borrower may be by a Lender that is a SBIC. Addendum 2 to this Agreement outlines various responsibilities of Agent, each Lender and Borrower associated with a loan made by a SBIC, and such Addendum 2 is hereby incorporated in this Agreement.

7.16 Use of Proceeds. Borrower agrees that the proceeds of the Loans shall be used solely to pay related fees and expenses in connection with this Agreement and for working capital and general corporate purposes. The proceeds of the Loans will not be used in violation of Anti-Corruption Laws or applicable Sanctions.

7.17 Material Agreement. Borrower shall (a) not, without the consent of Agent, terminate the Amgen License or amend the Amgen License in a manner that is reasonably likely to have a material negative impact on Agent or the Lenders, and (b) give prompt written notice to Agent of entering into a Material Agreement or materially amending or terminating a Material Agreement.

7.18 Compliance with Laws.

(a) Borrower shall maintain, and shall cause its Subsidiaries to maintain, compliance in all material respects with all applicable laws, rules or regulations (including any law, rule or regulation with respect to the making or brokering of loans or financial accommodations), and shall, or cause its Subsidiaries to, obtain and maintain all required governmental authorizations, approvals, licenses, franchises, permits or registrations reasonably necessary in connection with the conduct of Borrower's business. Borrower shall not become an "investment company" or a company controlled by an "investment company", under the Investment Company Act of 1940, as amended, or undertake as one of its important activities extending credit to purchase or carry margin stock (as defined in Regulation X, T and U of the Federal Reserve Board of Governors).

(b) Neither Borrower nor any of its Subsidiaries shall, nor shall Borrower or any of its Subsidiaries permit any Affiliate to, directly or indirectly, knowingly enter into any documents, instruments, agreements or contracts with any Person listed on the OFAC Lists. Neither Borrower nor any of its Subsidiaries shall, nor shall Borrower or any of its Subsidiaries, permit any Affiliate to, directly or indirectly, (i) conduct any business or engage in any transaction or dealing with any Blocked Person, including, without limitation, the making or receiving of any contribution of funds, goods or services to or for the benefit of any Blocked Person, (ii) deal in, or otherwise engage in any transaction relating to, any property or interests in property blocked pursuant to Executive Order No. 13224 or any similar executive order or other Anti-Terrorism Law, or (iii) engage in or conspire to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding, or attempts to violate, any of the prohibitions set forth in Executive Order No. 13224 or other Anti-Terrorism Law.

(c) Borrower has implemented and shall maintain in effect policies and procedures designed to ensure compliance by the Borrower, its Subsidiaries and their respective directors, officers, employees and agents with Anti-Corruption Laws and applicable Sanctions, and Borrower, its Subsidiaries and their respective officers and employees and to the knowledge of Borrower its directors and agents, are in compliance with Anti-Corruption Laws and applicable Sanctions in all material respects.

(d) None of Borrower, any of its Subsidiaries or any of their respective directors, officers or employees, or to the knowledge of Borrower, any agent for Borrower or its Subsidiaries that will act in any capacity in connection with or benefit from the credit facility established hereby, is a Sanctioned Person. No Loan, use of proceeds or other transaction contemplated by this Agreement will violate Anti-Corruption Laws or applicable Sanctions.

7.19 Minimum Cash. Beginning on April 1, 2023 and at all times thereafter, Borrower shall maintain Qualified Cash in an amount greater than or equal to (x) the outstanding principal amount of the Term Loan Advances, multiplied by (y) (i) at all times prior to the Tranche III Milestone Date, 60% and (ii) at all times after the Tranche III Milestone Date, 50%.

7.20 Intellectual Property. Each Borrower shall (i) protect, defend and maintain the validity and enforceability of its Intellectual Property material to the operation or conduct of the business of Borrower; (ii) promptly advise Agent in writing of material infringements of its Intellectual Property which has any material value; and (iii) not allow any Intellectual Property material to Borrowers' business to be abandoned, forfeited or dedicated to the public without Agent's written consent.

1.5 Transactions with Affiliates. Except as otherwise described on Schedule 7.20 on the Closing Date, Borrower shall not and shall not permit any Subsidiary to, directly or indirectly, enter into or permit to exist any transaction of any kind with any Affiliate of Borrower or such Subsidiary on terms that are less favorable to Borrower or such Subsidiary, as the case may be, than those that might be obtained in an arm's length transaction from a Person who is not an Affiliate of Borrower or such Subsidiary.

1.6 Permitted Convertible Debt Financing. (a) Make or permit any payment on Permitted Convertible Debt Financing except (i) interest payments to the extent otherwise permitted by this Agreement and (ii) the Borrower's delivery of conversion consideration in connection with the conversion by holders of any Permitted Convertible Debt Financing in accordance with the terms of the indenture governing such Permitted Convertible Debt Financing or the delivery of common stock and Cash in lieu of fractional shares of Common Stock to induce the conversion of Permitted Convertible Notes; provided that the conversion consideration (or inducement consideration) paid to such holders is limited to (A) Common Stock and (B) Cash in lieu of fractional shares of Common Stock (provided further that the amount of Cash in lieu of fractional shares of Common Stock paid to holders of Permitted Convertible Debt Financing in connection with the conversion thereof, or the inducement to convert Permitted Convertible Debt Financing, shall not exceed Two Hundred Fifty Thousand Dollars ($250,000) in the aggregate in any fiscal year of the Borrower), or (b) redeem or repurchase any Permitted Convertible Debt Financing (other than the repurchase of Permitted Convertible Debt Financing in exchange for Common Stock and Cash in lieu of fractional shares of Common Stock); provided that the repurchase consideration paid to the holders of Permitted Convertible Debt Financing is limited to (A) Common Stock and (B) Cash in lieu of fractional shares of Common Stock (provided further that the amount of Cash in lieu of fractional shares of Common Stock paid to holders of Permitted Convertible Debt Financing in connection with the repurchase

thereof shall not exceed Two Hundred Fifty Thousand Dollars ($250,000) in the aggregate in any fiscal year of the Borrower). In no event shall the foregoing permit Borrower to pay holders of Permitted Convertible Debt Financing Cash in connection with mandatory repurchase rights granted to such holders upon the occurrence of a "change of control", "fundamental change", "make-whole fundamental change" or any comparable term.

1.7 MSC Investment Conditions. At any time that the MSC Subsidiary has any assets or liabilities, Borrower shall satisfy the MSC Investment Conditions at all times.

1.8 Post-Closing Obligation. Within thirty (30) days after the Closing Date, Borrower shall have delivered to Agent policies and endorsements with respect to the insurance of the Loan Parties in accordance with the requirements of Section 6.2.

SECTION 8. RIGHT TO INVEST

8.1 Right to Invest. The Lenders or their assignee or nominee shall have the right, in its discretion, to participate in any Subsequent Financing in an amount of up to five percent (5%) of the offered sum for such Subsequent Financing, on the same terms, conditions and pricing afforded to others participating in any such Subsequent Financing. Akero Therapeutics, or an investment bank or underwriter engaged on Akero Therapeutics' behalf, shall provide the Lenders or their permitted assignees or nominees at least three (3) Business Days' written notice of any planned Subsequent Financing and the opportunity to exercise the right to invest under this Section 8.1 with respect to any such Subsequent Financing. This Section 8.1, and all rights and obligations hereunder, shall terminate upon the earliest to occur of (a) termination of this Agreement or (b) such time that the Lenders or their permitted assignees or nominees have purchased Ten Million Dollars ($10,000,000) of Akero Therapeutics' Equity Interests in the aggregate in Subsequent Financings.

SECTION 9. EVENTS OF DEFAULT

The occurrence of any one or more of the following events shall be an Event of Default:

9.1 Payments. Borrower fails to pay any (i) scheduled payment of principal or interest due under this Agreement or any of the other Loan Documents on the due date or (ii) other payment due on the Secured Obligations hereunder within three (3) Business Days; provided, however, that an Event of Default shall not occur on account of a failure to pay due solely to an administrative or operational error of Agent or the Lenders or Borrower's bank if Borrower had the funds to make the payment when due and makes the payment within three (3) Business Days following Borrower's knowledge of such failure to pay; or

9.2 Covenants. Borrower breaches or defaults in the performance of any covenant or Secured Obligation under this Agreement, or any of the other Loan Documents or any other agreement among Borrower, Agent and the Lenders, and (a) with respect to a default under any covenant under this Agreement (other than under Sections 6, 7.4, 7.5, 7.6, 7.7, 7.8, 7.9, 7.14, 7.15, 7.16, 7.18, 7.19, 7.20, and 7.21), any other Loan Document, or any other agreement among Borrower, Agent and the Lenders, such default continues for more than ten (10) days after the earlier of the date on which (i) Agent or the Lenders has given notice of such default to Borrower and (ii) Borrower has actual knowledge of such default or (b) with respect to a default under any of Sections 6, 7.4, 7.5, 7.6, 7.7, 7.8, 7.9, 7.14, 7.15, 7.16, 7.18, 7.19, 7.20, and 7.21, the occurrence of such default; or

9.3 Material Adverse Effect. A circumstance has occurred that could reasonably be expected to have a Material Adverse Effect (other than as a result of a failure by Agent to make any necessary filings or maintain possession of any possessory collateral); or

9.4 Representations. Any representation or warranty made by Borrower in any Loan Document or in the Warrant shall have been false or misleading in any material respect when made or when deemed made; or

9.5 Insolvency. Borrower (A) (i) shall make an assignment for the benefit of creditors; or (ii) shall be unable to pay its debts as they become due, or be unable to pay or perform under the Loan Documents, or shall become insolvent; or (iii) shall file a voluntary petition in bankruptcy; or (iv) shall file any petition, answer, or document seeking for itself any reorganization, arrangement, composition, readjustment, liquidation, dissolution or similar relief under any present or future statute, law or regulation pertinent to such circumstances except as permitted under Section 7.10; or (v) shall seek or consent to or acquiesce in the appointment of any trustee, receiver, or liquidator of Borrower or of all or any substantial part (i.e., 33-1/3% or more) of the assets or property of Borrower; or (vi) shall cease operations of its business as its business has normally been conducted, or terminate substantially all of its employees; or (vii) Borrower or its directors or majority shareholders shall take any action initiating any of the foregoing actions described in clauses (i) through (vi); or (B) either (i) forty-five (45) days shall have expired after the commencement of an involuntary action against Borrower seeking reorganization, arrangement, composition, readjustment, liquidation, dissolution or similar relief under any present or future statute, law or regulation, without such action being dismissed or all orders or proceedings thereunder affecting the operations or the business of Borrower being stayed; or (ii) a stay of any such order or proceedings shall thereafter be set aside and the action setting it aside shall not be timely appealed; or (iii) Borrower shall file any answer admitting or not contesting the material allegations of a petition filed against Borrower in any such proceedings; or (iv) the court in which such proceedings are pending shall enter a decree or order granting the relief sought in any such proceedings; or (v) forty-five (45) days shall have expired after the appointment, without the consent or acquiescence of Borrower, of any trustee, receiver or liquidator of Borrower or of all or any substantial part of the properties of Borrower without such appointment being vacated; or

9.6 Attachments; Judgments. Any portion of Borrower's assets is attached or seized, or a levy is filed against any such assets, or a judgment or judgments either by a court of competent jurisdiction or by a regulatory agency with the power to do so is/are entered for the payment of money (not covered by independent third party insurance as to which liability has not been rejected by such insurance carrier), individually or in the aggregate, of at least One Million Dollars ($1,000,000), or Borrower is enjoined or in any way prevented by court order from conducting any part of its business; or

9.7 Other Obligations. The occurrence and continuation of any default that exists beyond any applicable grace and/or cure periods under any agreement or obligation of Borrower involving any Indebtedness in excess of Five Hundred Thousand Dollars ($500,000), or any other material agreement or obligation, if a Material Adverse Effect could reasonably be expected to result from such default.

1.9 Stop Trade. At any time, an SEC stop trade order or NASDAQ market trading suspension of the Common Stock shall be in effect for five (5) consecutive days or five (5) days during a period of ten (10) consecutive days, excluding in all cases a suspension of all trading on a public market, provided that Borrower shall not have been able to cure such trading suspension

within thirty (30) days of the notice thereof or list the Common Stock on another public market within sixty (60) days of such notice.

SECTION 10. REMEDIES

10.1 General. Upon the occurrence and during the continuance of any one or more Events of Default, to the extent not prohibited by applicable law, Agent may, and at the direction of the Required Lenders shall, accelerate and demand payment of all or any part of the Secured Obligations together with any applicable Prepayment Charge and declare them to be immediately due and payable (provided, that upon the occurrence of an Event of Default of the type described in Section 9.5, all of the outstanding Secured Obligations (including, without limitation, the Prepayment Charge and the End of Term Charge) shall automatically be accelerated and made due and payable, in each case without any further notice or act). Borrower hereby irrevocably appoints Agent as its lawful attorney-in-fact to, only exercisable following the occurrence and during the continuance of an Event of Default: (i) sign Borrower's name on any invoice or bill of lading for any account or drafts against account debtors; (ii) demand, collect, sue, and give releases to any account debtor for monies due, settle and adjust disputes and claims about the accounts directly with account debtors, and compromise, prosecute, or defend any action, claim, case, or proceeding about any Collateral (including filing a claim or voting a claim in any bankruptcy case in Agent's or Borrower's name, as Agent may elect); (iii) make, settle, and adjust all claims under Borrower's insurance policies; (iv) pay, contest or settle any Lien, charge, encumbrance, security interest, or other claim in or to the Collateral, or any judgment based thereon, or otherwise take any action to terminate or discharge the same; (v) transfer the Collateral into the name of Agent or a third party as the UCC permits; (vi) receive, open and dispose of mail addressed to Borrower; (vii) endorse Borrower's name on any checks, payment instruments, or other forms of payment or security; and (viii) notify all account debtors to pay Agent directly. Borrower hereby appoints Agent as its lawful attorney-in-fact to sign Borrower's name on any documents necessary to perfect or continue the perfection of Agent's security interest in the Collateral regardless of whether an Event of Default has occurred until all outstanding Secured Obligations have been satisfied in full and the Loan Documents (other than the Warrant) have been terminated. Agent's foregoing appointment as Borrower's attorney in fact, and all of Agent's rights and powers, coupled with an interest, are irrevocable until all Secured Obligations (other than inchoate indemnity or reimbursement obligations and any other obligations which, by their terms, are to survive the termination of this Agreement) have been fully repaid and performed and the Loan Documents have been terminated. Agent may, and at the direction of the Required Lenders shall, exercise all rights and remedies with respect to the Collateral under the Loan Documents (other than the Warrant) or otherwise available to it under the UCC and other applicable law, including the right to release, hold, sell, lease, liquidate, collect, realize upon, or otherwise dispose of all or any part of the Collateral and the right to occupy, utilize, process and commingle the Collateral. All Agent's rights and remedies shall be cumulative and not exclusive.

10.2 Collection; Foreclosure. Upon the occurrence and during the continuance of any Event of Default, Agent may, and at the direction of the Required Lenders shall, at any time or from time to time, apply, collect, liquidate, sell in one or more sales, lease or otherwise dispose of, any or all of the Collateral, in its then condition or following any commercially reasonable preparation or processing, in such order as Agent may elect. Any such sale may be made either at public or private sale at its place of business or elsewhere. Borrower agrees that any such public or private sale may occur upon ten (10) calendar days' prior written notice to Borrower. Agent may require Borrower to assemble the Collateral and make it available to Agent at a place designated by Agent that is reasonably convenient to Agent and Borrower. The proceeds of any sale, disposition or other

realization upon all or any part of the Collateral shall be applied by Agent in the following order of priorities:

First, to Agent and the Lenders in an amount sufficient to pay in full Agent's and the Lenders' reasonable and documented out-of-pocket costs and professionals' and advisors' fees and expenses as described in Section 11.12;

Second, to the Lenders, ratably, in an amount equal to the then unpaid amount of the Secured Obligations (including principal, interest, and the Default Rate interest, if required under this Agreement), in such order and priority as Agent may choose in its sole discretion; and

Finally, after the full and final payment in Cash of all of the Secured Obligations (other than inchoate obligations), to any creditor holding a junior Lien on the Collateral, or to Borrower or its representatives or as a court of competent jurisdiction may direct.

Agent shall be deemed to have acted reasonably in the custody, preservation and disposition of any of the Collateral if it complies with the obligations of a secured party under the UCC.

10.3 No Waiver. Agent shall be under no obligation to marshal any of the Collateral for the benefit of Borrower or any other Person, and Borrower expressly waives all rights, if any, to require Agent to marshal any Collateral.

10.4 Waivers. Borrower waives demand, notice of default or dishonor, notice of payment and nonpayment, notice of any default, nonpayment at maturity, release, compromise, settlement, extension, or renewal of accounts, documents, instruments, chattel paper, and guarantees held by Agent on which Borrower is liable.

10.5 Cumulative Remedies. The rights, powers and remedies of Agent hereunder shall be in addition to all rights, powers and remedies given by statute or rule of law and are cumulative. The exercise of any one or more of the rights, powers and remedies provided herein shall not be construed as a waiver of or election of remedies with respect to any other rights, powers and remedies of Agent.

SECTION 11. MISCELLANEOUS

11.1 Severability. Whenever possible, each provision of this Agreement shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement shall be prohibited by or invalid under such law, such provision shall be ineffective only to the extent and duration of such prohibition or invalidity, without invalidating the remainder of such provision or the remaining provisions of this Agreement.

11.2 Notice. Except as otherwise provided herein, any notice, demand, request, consent, approval, declaration, service of process or other communication (including the delivery of Financial Statements) that is required, contemplated, or permitted under the Loan Documents or with respect to the subject matter hereof shall be in writing, and shall be deemed to have been validly served, given, delivered, and received upon the earlier of: (i) the day of transmission by electronic mail or hand delivery or delivery by an overnight express service or overnight mail delivery service; or (ii) the third calendar day after deposit in the United States of America mails, with proper first class postage prepaid, in each case addressed to the party to be notified as follows:

(a) If to Agent:

HERCULES CAPITAL, INC.
Legal Department
Attention: Chief Legal Officer, Cristy Barnes, Himani Bhalla and Briana Gironda
400 Hamilton Avenue, Suite 310
Palo Alto, CA 94301
email: [***]
Telephone: [***]

(b) If to the Lenders:

HERCULES CAPITAL, INC.
Legal Department
Attention: Chief Legal Officer, Cristy Barnes, Himani Bhalla and Briana Gironda
400 Hamilton Avenue, Suite 310
Palo Alto, CA 94301
email: [***]
Telephone: [***]

(c) If to Borrower:

AKERO THERAPEUTICS, INC.
Attention: Jonathan M. Young, Chief Operating Officer; William White, Chief Financial Officer
601 Gateway Blvd, Suite 350
South San Francisco, CA 94080
email: [***]
Telephone: [***]

or to such other address as each party may designate for itself by like notice.

11.3 Entire Agreement; Amendments.

(a) This Agreement and the other Loan Documents constitute the entire agreement and understanding of the parties hereto in respect of the subject matter hereof and thereof, and supersede and replace in their entirety any prior proposals, term sheets, non-disclosure or confidentiality agreements, letters, negotiations or other documents or agreements, whether written or oral, with respect to the subject matter hereof or thereof (including Agent's proposal letter dated May 20, 2022 and accepted by Borrower on May 20, 2022 and the Non-Disclosure Agreement).

(b) Neither this Agreement, any other Loan Document, nor any terms hereof or thereof may be amended, supplemented or modified except in accordance with the provisions of this Section 11.3(b). The Required Lenders and Borrower party to the relevant Loan Document may, or, with the written consent of the Required Lenders, the Agent and the Borrower party to the relevant Loan Document may, from time to time, (i) enter into written amendments, supplements or modifications hereto and to the other Loan Documents for the purpose of adding any provisions to this Agreement or the other Loan Documents or changing in any manner the rights of the Lenders or of the Borrower hereunder or thereunder or (ii) waive, on such terms and conditions as the Required Lenders or the Agent, as the case may be, may specify in such instrument, any of the requirements of this Agreement or the other Loan Documents or any Default or Event of Default

and its consequences; provided, however, that no such waiver and no such amendment, supplement or modification shall (A) forgive the principal amount or extend the final scheduled date of maturity of any Loan, extend the scheduled date of any amortization payment in respect of any Term Loan Advance, reduce the stated rate of any interest (or fee payable hereunder) or extend the scheduled date of any payment thereof, in each case without the written consent of each Lender directly affected thereby; (B) eliminate or reduce the voting rights of any Lender under this Section 11.3(b) without the written consent of such Lender; (C) reduce any percentage specified in the definition of Required Lenders, consent to the assignment or transfer by the Borrower of any of its rights and obligations under this Agreement and the other Loan Documents, release all or substantially all of the Collateral or release a Borrower from its obligations under the Loan Documents, in each case without the written consent of all Lenders; or (D) amend, modify or waive any provision of Section 11.18 or Addendum 3 without the written consent of the Agent. Any such waiver and any such amendment, supplement or modification shall apply equally to each Lender and shall be binding upon Borrower, the Lenders, the Agent and all future holders of the Loans.

11.4 No Strict Construction. The parties hereto have participated jointly in the negotiation and drafting of this Agreement. In the event an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as if drafted jointly by the parties hereto and no presumption or burden of proof shall arise favoring or disfavoring any party by virtue of the authorship of any provisions of this Agreement.

11.5 No Waiver. The powers conferred upon Agent and the Lenders by this Agreement are solely to protect their rights hereunder and under the other Loan Documents and their interest in the Collateral and shall not impose any duty upon Agent or the Lenders to exercise any such powers. No omission or delay by Agent or the Lenders at any time to enforce any right or remedy reserved to them, or to require performance of any of the terms, covenants or provisions hereof by Borrower at any time designated, shall be a waiver of any such right or remedy to which Agent or the Lenders is entitled, nor shall it in any way affect the right of Agent or the Lenders to enforce such provisions thereafter.

11.6 Survival. All agreements, representations and warranties contained in this Agreement and the other Loan Documents or in any document delivered pursuant hereto or thereto shall be for the benefit of Agent and the Lenders and shall survive the execution and delivery of this Agreement for so long as any Secured Obligations (other than any inchoate indemnity or reimbursement obligations and any other obligations which, by their terms, are to survive the termination of this Agreement) remain outstanding. Sections 6.3, 11.9, 11.11, 11.14, 11.15 and 11.17 shall survive the termination of this Agreement.

11.7 Successors and Assigns. The provisions of this Agreement and the other Loan Documents shall inure to the benefit of and be binding on Borrower and its permitted assigns (if any). Borrower shall not assign its obligations under this Agreement or any of the other Loan Documents without Agent’s express prior written consent, and any such attempted assignment shall be void and of no effect. Agent and the Lenders may assign, transfer, or endorse its rights hereunder and under the other Loan Documents with prior notice to Borrower (except if an Event of Default has occurred and is continuing or such assignment is to an Affiliate of Lender or Agent, in which case no notice shall be required), and all of such rights shall inure to the benefit of Agent’s and the Lenders’ successors and assigns; provided that as long as no Event of Default has occurred and is continuing, neither Agent nor any Lender may assign, transfer or endorse its rights hereunder or under the Loan Documents to any party that is a direct competitor of Borrower (as reasonably determined by Agent upon consultation with Borrower), it being acknowledged that in all cases, any

transfer to an Affiliate of any Lender or Agent shall be allowed. Notwithstanding the foregoing, (x) in connection with any assignment by a Lender as a result of a forced divestiture at the request of any regulatory agency, the restrictions set forth herein shall not apply and Agent and the Lenders may assign, transfer or indorse its rights hereunder and under the other Loan Documents to any Person or party and (y) in connection with a Lender's own financing or securitization transactions, the restrictions set forth herein shall not apply and Agent and the Lenders may assign, transfer or indorse its rights hereunder and under the other Loan Documents to any Person or party providing such financing or formed to undertake such securitization transaction and any transferee of such Person or party upon the occurrence of a default, event of default or similar occurrence with respect to such financing or securitization transaction; provided that no such sale, transfer, pledge or assignment under this clause (y) shall release such Lender from any of its obligations hereunder or substitute any such Person or party for such Lender as a party hereto until Agent shall have received and accepted an effective assignment agreement from such Person or party in form satisfactory to Agent executed, delivered and fully completed by the applicable parties thereto, and shall have received such other information regarding such assignee as Agent reasonably shall require. The Agent, acting solely for this purpose as an agent of the Borrower, shall maintain at one of its offices in the United States a register for the recordation of the names and addresses of the Lender(s), and the Term Commitments of, and principal amounts (and stated interest) of the Loans owing to, each Lender pursuant to the terms hereof from time to time (the "Register"). The entries in the Register shall be conclusive absent manifest error, and the Borrower, the Agent and the Lender(s) shall treat each Person whose name is recorded in the Register pursuant to the terms hereof as a Lender hereunder for all purposes of this Agreement. The Register shall be available for inspection by the Borrower and any Lender, at any reasonable time and from time to time upon reasonable prior notice.

11.8 Participations. Each Lender that sells a participation shall, acting solely for this purpose as a non-fiduciary agent of the Borrower, maintain a register on which it enters the name and address of each participant and the principal amounts (and stated interest) of each participant's interest in the Loans or other obligations under the Loan Documents (the "Participant Register"); provided that no Lender shall have any obligation to disclose all or any portion of the Participant Register (including the identity of any participant or any information relating to a participant's interest in any commitments, loans, its other obligations under any Loan Document) to any Person except to the extent that such disclosure is necessary to establish that such commitment, loan, letter of credit or other obligation is in registered form under Section 5f.103-1(c) of the United States Treasury Regulations. The entries in the Participant Register shall be conclusive absent manifest error, and such Lender shall treat each Person whose name is recorded in the Participant Register as the owner of such participation for all purposes of this Agreement notwithstanding any notice to the contrary. For the avoidance of doubt, the Agent (in its capacity as Agent) shall have no responsibility for maintaining a Participant Register. Borrower agrees that each participant shall be entitled to the benefits of the provisions in Addendum 1 attached hereto (subject to the requirements and limitations therein, including the requirements under Section 7 of Addendum 1 attached hereto (it being understood that the documentation required under Section 7 of Addendum 1 attached hereto shall be delivered to the participating Lender)) to the same extent as if it were a Lender and had acquired its interest by assignment pursuant to Section 11.7; provided that such participant shall not be entitled to receive any greater payment under Addendum 1 attached hereto, with respect to any participation, than its participating Lender would have been entitled to receive, except to the extent such entitlement to receive a greater payment results from a change in law that occurs after the participant acquired the applicable participation.

11.9 Governing Law. This Agreement and the other Loan Documents have been negotiated and delivered to Agent and the Lenders in the State of California, and shall have been

accepted by Agent and the Lenders in the State of California. Payment to Agent and the Lenders by Borrower of the Secured Obligations is due in the State of California. This Agreement and the other Loan Documents (other than the Warrant) shall be governed by, and construed and enforced in accordance with, the laws of the State of California, excluding conflict of laws principles that would cause the application of laws of any other jurisdiction.

11.10 Consent to Jurisdiction and Venue. All judicial proceedings (to the extent that the reference requirement of Section 11.11 is not applicable) arising in or under or related to this Agreement or any of the other Loan Documents may be brought in any state or federal court located in the State of California. By execution and delivery of this Agreement, each party hereto generally and unconditionally: (a) consents to nonexclusive personal jurisdiction in Santa Clara County, State of California; (b) waives any objection as to jurisdiction or venue in Santa Clara County, State of California; (c) agrees not to assert any defense based on lack of jurisdiction or venue in the aforesaid courts; and (d) irrevocably agrees to be bound by any judgment rendered thereby in connection with this Agreement or the other Loan Documents. Service of process on any party hereto in any action arising out of or relating to this Agreement shall be effective if given in accordance with the requirements for notice set forth in Section 11.2, and shall be deemed effective and received as set forth in Section 11.2. Nothing herein shall affect the right to serve process in any other manner permitted by law or shall limit the right of either party to bring proceedings in the courts of any other jurisdiction.

11.11 Mutual Waiver of Jury Trial / Judicial Reference.

(a) Because disputes arising in connection with complex financial transactions are most quickly and economically resolved by an experienced and expert Person and the parties wish applicable state and federal laws to apply (rather than arbitration rules), the parties desire that their disputes be resolved by a judge applying such applicable laws. EACH OF BORROWER, AGENT AND THE LENDERS SPECIFICALLY WAIVES ANY RIGHT IT MAY HAVE TO TRIAL BY JURY OF ANY CAUSE OF ACTION, CLAIM, CROSS-CLAIM, COUNTERCLAIM, THIRD PARTY CLAIM OR ANY OTHER CLAIM (COLLECTIVELY, "CLAIMS") ASSERTED BY BORROWER AGAINST AGENT, THE LENDERS OR THEIR RESPECTIVE ASSIGNEE OR BY AGENT, THE LENDERS OR THEIR RESPECTIVE ASSIGNEE AGAINST BORROWER. This waiver extends to all such Claims, including Claims that involve Persons other than Agent, Borrower and the Lenders; Claims that arise out of or are in any way connected to the relationship among Borrower, Agent and the Lenders; and any Claims for damages, breach of contract, tort, specific performance, or any equitable or legal relief of any kind, arising out of this Agreement, any other Loan Document (other than to the extent arising from Agent's or any Lender's breach of the Loan Documents, gross negligence or willful misconduct).

(b) If the waiver of jury trial set forth in Section 11.11(a) is ineffective or unenforceable, the parties agree that all Claims shall be resolved by reference to a private judge sitting without a jury, pursuant to Code of Civil Procedure Section 638, before a mutually acceptable referee or, if the parties cannot agree, a referee selected by the Presiding Judge of the Santa Clara County, California. Such proceeding shall be conducted in Santa Clara County, California, with California rules of evidence and discovery applicable to such proceeding.

(c) In the event Claims are to be resolved by judicial reference, either party may seek from a court identified in Section 11.10, any prejudgment order, writ or other relief and have such prejudgment order, writ or other relief enforced to the fullest extent permitted by law notwithstanding that all Claims are otherwise subject to resolution by judicial reference.

11.12 Professional Fees. Borrower promises to pay Agent's and the Lenders' reasonable and documented out-of-pocket fees and expenses necessary to finalize the Loan Documents, including but not limited to reasonable and documented out-of-pocket attorneys' fees, UCC searches, filing costs, and other miscellaneous expenses. In addition, Borrower promises to pay any and all reasonable and documented out-of-pocket attorneys' and other professionals' fees and expenses incurred by Agent and the Lenders after the Closing Date in connection with or related to: (a) the Loan; (b) the administration, collection, or enforcement of the Loan; (c) the amendment or modification of the Loan Documents; (d) any waiver, consent, release, or termination under the Loan Documents; (e) the protection, preservation, audit, field exam, sale, lease, liquidation, or disposition of Collateral or the exercise of remedies with respect to the Collateral; (f) any legal, litigation, administrative, arbitration, or out of court proceeding in connection with or related to Borrower or the Collateral, and any appeal or review thereof; and (g) any bankruptcy, restructuring, reorganization, assignment for the benefit of creditors, workout, foreclosure, or other action related to Borrower, the Collateral, the Loan Documents, including representing Agent or the Lenders in any adversary proceeding or contested matter commenced or continued by or on behalf of Borrower's estate, and any appeal or review thereof.

11.13 Confidentiality. Agent and the Lenders acknowledge that certain items of Collateral and information provided to Agent and the Lenders by Borrower are confidential and proprietary information of Borrower, if and to the extent such information either (x) is marked as confidential by Borrower at the time of disclosure, or (y) should reasonably be understood to be confidential (the "Confidential Information"). Accordingly, Agent and the Lenders agree that any Confidential Information it may obtain in the course of acquiring, administering, or perfecting Agent's security interest in the Collateral shall not be disclosed to any other Person or entity in any manner whatsoever, in whole or in part, without the prior written consent of Borrower, except that Agent and the Lenders may disclose any such information: (a) to its Affiliates and its partners, investors, lenders, directors, officers, employees, agents, advisors, counsel, accountants, representative and other professional advisors if Agent or the Lenders in their reasonable discretion determines that any such party should have access to such information in connection with such party's responsibilities in connection with the Loan or this Agreement and, provided that such recipient of such Confidential Information either (i) agrees to be bound by the confidentiality provisions of this paragraph or (ii) is otherwise subject to confidentiality restrictions that reasonably protect against the disclosure of Confidential Information which are no less restrictive than the terms of this Section 11.13; (b) if such information is generally available to the public or to the extent such information becomes publicly available other than as a result of a breach of this Section or becomes available to Agent or any Lender, or any of their respective Affiliates on a non-confidential basis from a source other than the Borrower; (c) if required or appropriate in any report, statement or testimony submitted to any governmental authority having or claiming to have jurisdiction over Agent or the Lenders and any rating agency; (d) if required or appropriate in response to any summons or subpoena or in connection with any litigation, to the extent permitted or deemed advisable by Agent's or the Lenders' counsel; (e) to comply with any legal requirement or law applicable to Agent or the Lenders or demanded by any governmental authority; (f) to the extent reasonably necessary in connection with the exercise of, or preparing to exercise, or the enforcement of, or preparing to enforce, any right or remedy under any Loan Document (including Agent's sale, lease, or other disposition of Collateral after the occurrence and the continuance of an Event of Default), or any action or proceeding relating to any Loan Document; (g) to any participant or assignee of Agent or the Lenders or any prospective participant or assignee, provided, that such participant or assignee or prospective participant or assignee is subject to confidentiality restrictions that reasonably protect against the disclosure of Confidential Information which are no less restrictive than the terms of this Section 11.13; (h) to any investor or potential investor (and each of their respective Affiliates or clients) in

the Agent or Lenders (or each of their respective Affiliates); provided that such investor, potential investor, Affiliate or client is subject to confidentiality obligations with respect to the Confidential Information; (i) otherwise to the extent consisting of general portfolio information that does not identify Borrower; or (j) otherwise with the prior written consent of Borrower; provided, that any disclosure made in violation of this Agreement shall not affect the obligations of Borrower or any of its Affiliates or any guarantor under this Agreement or the other Loan Documents. Agent's and the Lenders' obligations under this Section 11.13 shall supersede all of their respective obligations under the Non-Disclosure Agreement.

11.14 Assignment of Rights. Borrower acknowledges and understands that Agent or the Lenders may, subject to Section 11.7, sell and assign all or part of its interest hereunder and under the Loan Documents to any Person or entity (an "Assignee"). After such assignment the term "Agent" or "Lender" as used in the Loan Documents shall mean and include such Assignee, and such Assignee shall be vested with all rights, powers and remedies of Agent and the Lenders hereunder with respect to the interest so assigned; but with respect to any such interest not so transferred, Agent and the Lenders shall retain all rights, powers and remedies hereby given. No such assignment by Agent or the Lenders shall relieve Borrower of any of its obligations hereunder. the Lenders agrees that in the event of any transfer by it of the promissory note(s) (if any), it will endorse thereon a notation as to the portion of the principal of the promissory note(s), which shall have been paid at the time of such transfer and as to the date to which interest shall have been last paid thereon.

11.15 Revival of Secured Obligations. This Agreement and the Loan Documents shall remain in full force and effect and continue to be effective if any petition is filed by or against Borrower for liquidation or reorganization, if Borrower becomes insolvent or makes an assignment for the benefit of creditors, if a receiver or trustee is appointed for all or any significant part of Borrower's assets, or if any payment or transfer of Collateral is recovered from Agent or the Lenders. The Loan Documents and the Secured Obligations and Collateral security shall continue to be effective, or shall be revived or reinstated, as the case may be, if at any time payment and performance of the Secured Obligations or any transfer of Collateral to Agent, or any part thereof is rescinded, avoided or avoidable, reduced in amount, or must otherwise be restored or returned by, or is recovered from, Agent, the Lenders or by any obligee of the Secured Obligations, whether as a "voidable preference," "fraudulent conveyance," or otherwise, all as though such payment, performance, or transfer of Collateral had not been made. In the event that any payment, or any part thereof, is rescinded, reduced, avoided, avoidable, restored, returned, or recovered, the Loan Documents and the Secured Obligations shall be deemed, without any further action or documentation, to have been revived and reinstated except to the extent of the full, final, and indefeasible payment to Agent or the Lenders in Cash.

11.16 Counterparts. This Agreement and any amendments, waivers, consents or supplements hereto may be executed in any number of counterparts, and by different parties hereto in separate counterparts, each of which when so delivered shall be deemed an original, but all of which counterparts shall constitute but one and the same instrument.

11.17 No Third Party Beneficiaries. No provisions of the Loan Documents are intended, nor will be interpreted, to provide or create any third-party beneficiary rights or any other rights of any kind in any Person other than Agent, the Lenders and Borrower unless specifically provided otherwise herein, and, except as otherwise so provided, all provisions of the Loan Documents will be personal and solely among Agent, the Lenders and the Borrower.

11.18 Agency. Agent and each Lender hereby agree to the terms and conditions set forth on Addendum 3 attached hereto. Borrower acknowledges and agrees to the terms and conditions set forth on Addendum 3 attached hereto.

11.19 Publicity. None of the parties hereto nor any of its respective member businesses and Affiliates shall, without the other parties' prior written consent, publicize or use (a) the other party's name (including a brief description of the relationship among the parties hereto), logo or hyperlink to such other parties' web site, separately or together, in written and oral presentations, advertising, promotional and marketing materials, client lists, public relations materials or on its web site (together, the "Publicity Materials"); (b) the names of officers of such other parties in the Publicity Materials; and (c) such other parties' name, trademarks, servicemarks in any news or press release concerning such party; provided however, notwithstanding anything to the contrary herein, no such consent shall be required (i) to the extent necessary to comply with the requests of any regulators, legal requirements or laws applicable to such party, pursuant to any listing agreement with any national securities exchange (so long as such party provides prior notice to the other party hereto to the extent reasonably practicable) and (ii) to comply with Section 11.13.

1.10 Multiple Borrowers. Each Borrower hereby agrees to the terms and conditions set forth on Addendum 4 attached hereto.

11.20 Electronic Execution of Certain Other Documents. The words "execution," "execute", "signed," "signature," and words of like import in or related to any document to be signed in connection with this Agreement and the transactions contemplated hereby (including without limitation assignments, assumptions, amendments, waivers and consents) shall be deemed to include electronic signatures, the electronic matching of assignment terms and contract formations on electronic platforms approved by the Agent, or the keeping of records in electronic form, each of which shall be of the same legal effect, validity or enforceability as a manually executed signature or the use of a paper-based recordkeeping system, as the case may be, to the extent and as provided for in any applicable law, including the Federal Electronic Signatures in Global and National Commerce Act, the California Uniform Electronic Transaction Act, or any other similar state laws based on the Uniform Electronic Transactions Act.

(SIGNATURES TO FOLLOW)

IN WITNESS WHEREOF, Borrower, Agent and the Lenders have duly executed and delivered this Loan and Security Agreement as of the day and year first above written.

BORROWER:

AKERO THERAPEUTICS, INC.

Signature: /s/ Andrew Cheng

Print Name: Andrew Cheng

Title: President and Chief Executive Officer

Accepted in Palo Alto, California:

AGENT:

HERCULES CAPITAL, INC.

Signature: /s/ Seth Meyer _____

Print Name: Seth Meyer

Title: Chief Financial Officer

LENDERS:

HERCULES CAPITAL, INC.

Signature: /s/ Seth Meyer_____

Print Name: Seth Meyer

Title: Chief Financial Officer

HERCULES PRIVATE GLOBAL VENTURE GROWTH FUND I L.P.

By: Hercules Adviser LLC, its Investment Adviser

Signature: /s/ Seth Meyer_____

Print Name: Seth Meyer

Title: Authorized Signatory

Schedule 5.10 Intellectual Property
Schedule 5.11 Borrower Products
Schedule 5.13 Employee Loans
Schedule 5.14 Capitalization
Schedule 7.20 Affiliate Transactions

ADDENDUM 1 to LOAN AND SECURITY AGREEMENT

TAXES; INCREASED COSTS

1. Defined Terms. For purposes of this Addendum 1:

a. "**Connection Income Taxes**" means Other Connection Taxes that are imposed on or measured by net income (however denominated) or that are franchise Taxes or branch profits Taxes.

b. "**Excluded Taxes**" means any of the following Taxes imposed on or with respect to a Recipient or required to be withheld or deducted from a payment to a Recipient, (i) Taxes imposed on or measured by net income (however denominated), franchise Taxes, and branch profits Taxes, in each case, (A) imposed as a result of such Recipient being organized under the laws of, or having its principal office or, in the case of any Lender, its applicable lending office located in, the jurisdiction imposing such Tax (or any political subdivision thereof) or (B) that are Other Connection Taxes, (ii) in the case of a Lender, U.S. federal withholding Taxes imposed on amounts payable to or for the account of such Lender with respect to an applicable interest in a Loan or Term Commitment pursuant to a law in effect on the date on which (A) such Lender acquires such interest in the Loan or Term Commitment or (B) such Lender changes its lending office, except in each case to the extent that, pursuant to Section 2 or Section 4 of this Addendum 1, amounts with respect to such Taxes were payable either to such Lender's assignor immediately before such Lender became a party hereto or to such Lender immediately before it changed its lending office, (iii) Taxes attributable to such Recipient's failure to comply with Section 7 of this Addendum 1 and (iv) any withholding Taxes imposed under FATCA.

c. "**FATCA**" means Sections 1471 through 1474 of the Code, as of the date of this Agreement (or any amended or successor version that is substantively comparable and not materially more onerous to comply with), any current or future regulations or official interpretations thereof, any agreements entered into pursuant to Section 1471(b)(1) of the Code, and any fiscal or regulatory legislation, rules or practices adopted pursuant to any intergovernmental agreement, treaty or convention among governmental authorities and implementing such Sections of the Code.

d. "**Foreign Lender**" means a Lender that is not a U.S. Person.

e. "**Indemnified Taxes**" means (i) Taxes, other than Excluded Taxes, imposed on or with respect to any payment made by or on account of any obligation of the Borrower under any Loan Document and (ii) to the extent not otherwise described in clause (i), Other Taxes.

f. "**Other Connection Taxes**" means, with respect to any Recipient, Taxes imposed as a result of a present or former connection between such Recipient and the jurisdiction imposing such Tax (other than connections arising from such Recipient having executed, delivered, become a party to, performed its obligations under, received payments under, received or perfected a security interest under, engaged in any other transaction pursuant to or enforced any Loan Document, or sold or assigned an interest in any Loan or Loan Document).

g. "**Other Taxes**" means all present or future stamp, court or documentary, intangible, recording, filing or similar Taxes that arise from any payment made under, from the execution, delivery,

performance, enforcement or registration of, from the receipt or perfection of a security interest under, or otherwise with respect to, any Loan Document, except any such Taxes that are Other Connection Taxes imposed with respect to an assignment.

h. "**Recipient**" means the Agent or any Lender, as applicable.

i. "**Withholding Agent**" means the Borrower and the Agent.

2. Payments Free of Taxes. Any and all payments by or on account of any obligation of the Borrower under any Loan Document shall be made without deduction or withholding for any Taxes, except as required by applicable law. If any applicable law (as determined in the good faith discretion of an applicable Withholding Agent) requires the deduction or withholding of any Tax from any such payment by a Withholding Agent, then the applicable Withholding Agent shall be entitled to make such deduction or withholding and shall timely pay the full amount deducted or withheld to the relevant governmental authority in accordance with applicable law and, if such Tax is an Indemnified Tax, then the sum payable by the Borrower shall be increased as necessary so that after such deduction or withholding has been made (including such deductions and withholdings applicable to additional sums payable under this Section 2 or Section 4 of this Addendum 1) the applicable Recipient receives an amount equal to the sum it would have received had no such deduction or withholding been made.

3. Payment of Other Taxes by Borrower. The Borrower shall timely pay to the relevant governmental authority in accordance with applicable law, or at the option of the Agent timely reimburse it for the payment of, any Other Taxes.

4. Indemnification by Borrower. The Borrower shall indemnify each Recipient, within 10 days after demand therefor, for the full amount of any Indemnified Taxes (including Indemnified Taxes imposed or asserted on or attributable to amounts payable under Section 2 of this Addendum 1 or this Section 4) payable or paid by such Recipient or required to be withheld or deducted from a payment to such Recipient and any reasonable expenses arising therefrom or with respect thereto, whether or not such Indemnified Taxes were correctly or legally imposed or asserted by the relevant governmental authority. A certificate describing the amount of such payment or liability delivered to the Borrower by a Lender (with a copy to the Agent), or by the Agent on its own behalf or on behalf of a Lender, shall be conclusive absent manifest error. In addition, the Borrower agrees to pay, and to save the Agent and any Lender harmless from, any and all liabilities with respect to, or resulting from any delay in paying, any and all excise, sales or other similar taxes (excluding taxes imposed on or measured by the net income of the Agent or such Lender) that may be payable or determined to be payable with respect to any of the Collateral or this Agreement.

5. Indemnification by the Lenders. Each Lender shall severally indemnify the Agent, within 10 days after demand therefor, for (a) any Indemnified Taxes attributable to such Lender (but only to the extent that the Borrower has not already indemnified the Agent for such Indemnified Taxes and without limiting the obligation of the Borrower to do so), (b) any Taxes attributable to such Lender's failure to comply with the provisions of Section 11.8 of the Agreement relating to the maintenance of a Participant Register and (c) any Excluded Taxes attributable to such Lender, in each case, that are payable or paid by the Agent in connection with any Loan Document, and any reasonable expenses arising therefrom or with respect thereto, whether or not such Taxes were correctly or legally imposed or asserted by the relevant governmental authority. A certificate as to the amount of such payment or liability delivered to any Lender by the Agent shall be conclusive absent manifest error. Each Lender hereby authorizes the Agent to set off and apply any and all amounts at any time owing to such Lender

under any Loan Document or otherwise payable by the Agent to the Lender from any other source against any amount due to the Agent under this Section 5.

6. Evidence of Payments. As soon as practicable after any payment of Taxes by the Borrower to a governmental authority pursuant to the provisions of this Addendum 1, the Borrower shall deliver to the Agent the original or a certified copy of a receipt issued by such governmental authority evidencing such payment, a copy of the return reporting such payment or other evidence of such payment reasonably satisfactory to the Agent.

7. Status of Lenders.

a. Any Lender that is entitled to an exemption from or reduction of withholding Tax with respect to payments made under any Loan Document shall deliver to the Borrower and the Agent, at the time or times reasonably requested by the Borrower or the Agent, such properly completed and executed documentation reasonably requested by the Borrower or the Agent as will permit such payments to be made without withholding or at a reduced rate of withholding. In addition, any Lender, if reasonably requested by the Borrower or the Agent, shall deliver such other documentation prescribed by applicable law or reasonably requested by the Borrower or the Agent as will enable the Borrower or the Agent to determine whether or not such Lender is subject to backup withholding or information reporting requirements. Notwithstanding anything to the contrary in the preceding two sentences, the completion, execution and submission of such documentation (other than such documentation set forth in Sections 7(b)(i), 7(b)(ii) and 7(b)(iv) of this Addendum 1) shall not be required if in the Lender's reasonable judgment such completion, execution or submission would subject such Lender to any material unreimbursed cost or expense or would materially prejudice the legal or commercial position of such Lender.

b. Without limiting the generality of the foregoing, in the event that the Borrower is a U.S. Person,

i. any Lender that is a U.S. Person shall deliver to the Borrower and the Agent on or prior to the date on which such Lender becomes a Lender under this Agreement (and from time to time thereafter upon the reasonable request of the Borrower or the Agent), executed copies of IRS Form W-9 certifying that such Lender is exempt from U.S. federal backup withholding tax;

ii. any Foreign Lender shall, to the extent it is legally entitled to do so, deliver to the Borrower and the Agent (in such number of copies as shall be requested by the recipient) on or prior to the date on which such Foreign Lender becomes a Lender under this Agreement (and from time to time thereafter upon the reasonable request of the Borrower or the Agent), whichever of the following is applicable:

A. in the case of a Foreign Lender claiming the benefits of an income tax treaty to which the United States is a party (x) with respect to payments of interest under any Loan Document, appropriately completed and executed copies of IRS Form W-8BEN or IRS Form W-8BEN-E establishing an exemption from, or reduction of, U.S. federal withholding Tax pursuant to the "interest" article of such tax treaty and (y) with respect to any other applicable payments under any Loan Document, appropriately completed and IRS Form W-8BEN or IRS Form W-8BEN-E establishing an exemption from, or reduction of,

U.S. federal withholding Tax pursuant to the "business profits" or "other income" article of such tax treaty;

B. appropriately completed and executed copies of IRS Form W-8ECI;

C. in the case of a Foreign Lender claiming the benefits of the exemption for portfolio interest under Section 881(c) of the Code, (x) a certificate substantially in the form of Exhibit J-1 to the effect that such Foreign Lender is not a "bank" within the meaning of Section 881(c)(3)(A) of the Code, a "10 percent shareholder" of the Borrower within the meaning of Section 871(h)(3)(B) of the Code, or a "controlled foreign corporation" related to the Borrower as described in Section 881(c)(3)(C) of the Code (a "**U.S. Tax Compliance Certificate**") and (y) executed copies of IRS Form W-8BEN or IRS Form W-8BEN-E; or

D. to the extent a Foreign Lender is not the beneficial owner, appropriately completed and executed copies of IRS Form W-8IMY, accompanied by appropriately completed and executed copies of IRS Form W-8ECI, IRS Form W-8BEN, IRS Form W-8BEN-E, a U.S. Tax Compliance Certificate substantially in the form of Exhibit J-2 or Exhibit J-3, IRS Form W-9, and/or other certification documents from each beneficial owner, as applicable; provided that if the Foreign Lender is a partnership and one or more direct or indirect partners of such Foreign Lender are claiming the portfolio interest exemption, such Foreign Lender may provide a U.S. Tax Compliance Certificate substantially in the form of Exhibit J-4 on behalf of each such direct and indirect partner;

iii. any Foreign Lender shall, to the extent it is legally entitled to do so, deliver to the Borrower and the Agent (in such number of copies as shall be requested by the recipient) on or prior to the date on which such Foreign Lender becomes a Lender under this Agreement (and from time to time thereafter upon the reasonable request of the Borrower or the Agent), executed copies of any other form prescribed by applicable law as a basis for claiming exemption from or a reduction in U.S. federal withholding Tax, duly completed, together with such supplementary documentation as may be prescribed by applicable law to permit the Borrower or the Agent to determine the withholding or deduction required to be made; and

iv. if a payment made to a Lender under any Loan Document would be subject to U.S. federal withholding Tax imposed by FATCA if such Lender were to fail to comply with the applicable reporting requirements of FATCA (including those contained in Section 1471(b) or 1472(b) of the Code, as applicable), such Lender shall deliver to the Borrower and the Agent at the time or times prescribed by law and at such time or times reasonably requested by the Borrower or the Agent such documentation prescribed by applicable law (including as prescribed by Section 1471(b)(3)(C)(i) of the Code) and such additional documentation reasonably requested by the Borrower or the Agent as may be necessary for the Borrower and the Agent to comply with their obligations under FATCA and to determine that such Lender has complied with such Lender's obligations under FATCA or to determine the amount, if any, to deduct and withhold from such payment. Solely for purposes of this clause (iv), "FATCA" shall include any amendments made to FATCA after the date of this Agreement.

c. Each Lender agrees that if any form or certification it previously delivered expires or becomes obsolete or inaccurate in any respect, it shall update such form or certification or promptly notify the Borrower and the Agent in writing of its legal inability to do so.

8. Treatment of Certain Refunds. If any party determines, in its sole discretion exercised in good faith, that it has received a refund of any Taxes as to which it has been indemnified pursuant to the provisions of this Addendum 1 (including by the payment of additional amounts pursuant to the provisions of this Addendum 1), it shall pay to the indemnifying party an amount equal to such refund (but only to the extent of indemnity payments made under the provisions of this Addendum 1 with respect to the Taxes giving rise to such refund), net of all reasonable and documented out-of-pocket expenses (including Taxes) of such indemnified party and without interest (other than any interest paid by the relevant governmental authority with respect to such refund). Such indemnifying party, upon the request of such indemnified party, shall repay to such indemnified party the amount paid over pursuant to this Section 8 (plus any penalties, interest or other charges imposed by the relevant governmental authority) in the event that such indemnified party is required to repay such refund to such governmental authority. Notwithstanding anything to the contrary in this Section 8, in no event will the indemnified party be required to pay any amount to an indemnifying party pursuant to this Section 8 the payment of which would place the indemnified party in a less favorable net after-Tax position than the indemnified party would have been in if the Tax subject to indemnification and giving rise to such refund had not been deducted, withheld or otherwise imposed and the indemnification payments or additional amounts with respect to such Tax had never been paid. This Section 8 shall not be construed to require any indemnified party to make available its Tax returns (or any other information relating to its Taxes that it deems confidential) to the indemnifying party or any other Person.

9. Increased Costs. If any change in applicable law shall subject any Recipient to any Taxes (other than (A) Indemnified Taxes, (B) Taxes described in clauses (ii) through (iv) of the definition of Excluded Taxes and (C) Connection Income Taxes) on its loans, loan principal, commitments, or other obligations, or its deposits, reserves, other liabilities or capital attributable thereto, and the result shall be to increase the cost to such Recipient of making, converting to, continuing or maintaining any Term Loan Advance or of maintaining its obligation to make any such Loan, or to reduce the amount of any sum received or receivable by such Recipient (whether of principal, interest or any other amount), then, upon the request of such Recipient, the Borrower will pay to such Recipient such additional amount or amounts as will compensate such Recipient for such additional costs incurred or reduction suffered.

10. Mitigation Obligations; Replacement of Lenders.

a. **Designation of a Different Lending Office**. If any Lender requests compensation under Section 9 of this Addendum 1, or requires the Borrower to pay any Indemnified Taxes or additional amounts to any Lender or any Governmental Authority for the account of any Lender pursuant to this Addendum 1, then such Lender shall (at the request of the Borrower) use reasonable efforts to designate a different lending office for funding or booking its Loans hereunder or to assign its rights and obligations hereunder to another of its offices, branches or affiliates, if, in the judgment of such Lender, such designation or assignment (i) would eliminate or reduce amounts payable by Borrower pursuant to this Addendum 1, as the case may be, in the future, and (ii) would not subject such Lender to any unreimbursed cost or expense and would not otherwise be disadvantageous to such Lender. The Borrower hereby agrees to pay all reasonable costs and expenses incurred by any Lender in connection with any such designation or assignment.

b. **Replacement of Lenders**. If the Borrower is required to pay any Indemnified Taxes or additional amounts to any Lender or any Governmental Authority for the account of any Lender pursuant to this Addendum 1 and, in each case, such Lender has declined or is unable to designate a different lending office in accordance with Section 10(a), or if a Lender fails to give its consent to any amendment, waiver or action for which consent of all Lenders was required and Required Lenders consented, then the Borrower may, at its sole expense and effort, upon notice to such Lender and Agent, require such Lender to assign and delegate, without recourse (in accordance with and subject to Section 11.7 of the Loan Agreement), all of its interests, rights (other than its existing rights to payments pursuant to this Addendum 1) and obligations under this Loan Agreement and the related Loan Documents to an Assignee that shall assume such obligations. Such Lender shall be entitled to receive, in cash, concurrently with such assignment, all amounts owed to it under the Loan Documents, including all principal, interest and fees through the date of assignment (but excluding any prepayment charge).

11. Survival. Each party's obligations under the provisions of this Addendum 1 shall survive the resignation or replacement of the Agent or any assignment of rights by, or the replacement of, a Lender, the termination of the Term Commitments and the repayment, satisfaction or discharge of all obligations under any Loan Document.

ADDENDUM 2 to LOAN AND SECURITY AGREEMENT

SBIC

(a) *Borrower's Business*. For purposes of this Addendum 2, Borrower shall be deemed to include its "affiliates" as defined in Title 13 Code of Federal Regulations Section 121.103. Borrower represents and warrants to Agent and the Lenders as of each SBA Funding Date and covenants to Agent and the Lenders for a period of one year after each SBA Funding Date or for such longer period as set forth below with respect to subsections 2, 3, 4, 5, 6 and 7 below, as follows:

1. Size Status. Borrower's primary NAICS code is 325412 and has less than 750 employees in the aggregate;

2. No Relender. Borrower's primary business activity does not involve, directly or indirectly, providing funds to others, purchasing debt obligations, factoring, or long-term leasing of equipment with no provision for maintenance or repair;

3. No Passive Business. Borrower is engaged in a regular and continuous business operation (excluding the mere receipt of payments such as dividends, rents, lease payments, or royalties). Borrower's employees are carrying on the majority of day to day operations. Borrower will not pass through substantially all of the proceeds of the Loan to another entity;

4. No Real Estate Business. Borrower is not classified under North American Industry Classification System (NAICS) codes 531110 (lessors of residential buildings and dwellings), 531120 (lessors of nonresidential buildings except miniwarehouses), 531190 (lessors of other real estate property), 237210 (land subdivision), or 236117 (new housing for-sale builders). Borrower is not classified under NAICS codes 236118 (residential remodelers), 236210 (industrial building construction), or 236220 (commercial and institutional building construction), if Borrower is primarily engaged in construction or renovation of properties on its own account rather than as a hired contractor. Borrower is not classified under NAICS codes 531210 (offices of real estate agents and brokers), 531311 (residential property managers), 531312 (nonresidential property managers), 531320 (offices of real estate appraisers), or 531390 (other activities related to real estate), unless it derives at least 80 percent of its revenue from non-Affiliate sources. The proceeds of the Loan will not be used to acquire or refinance real property unless Borrower (x) is acquiring an existing property and will use at least 51 percent of the usable square footage for its business purposes; (y) is building or renovating a building and will use at least 67 percent of the usable square footage for its business purposes; or (z) occupies the subject property and uses at least 67 percent of the usable square footage for its business purposes.

5. No Project Finance. Borrower's assets are not intended to be reduced or consumed, generally without replacement, as the life of its business progresses, and the nature of Borrower's business does not require that a stream of cash payments be made to the business's financing sources, on a

basis associated with the continuing sale of assets (e.g., real estate development projects and oil and gas wells). The primary purpose of the Loan is not to fund production of a single item or defined limited number of items, generally over a defined production period, where such production will constitute the majority of the activities of Borrower (e.g., motion pictures and electric generating plants).

6. No Farm Land Purchases. Borrower will not use the proceeds of the Loan to acquire farm land which is or is intended to be used for agricultural or forestry purposes, such as the production of food, fiber, or wood, or is so taxed or zoned.

7. No Foreign Investment. The proceeds of the Loan will not be used substantially for a foreign operation. Borrower will not have, on or within one year after each SBA Funding Date and each other Loan provided by a Lender that is an SBIC more than 49 percent of its employees or tangible assets located outside the United States of America.

(b) *Small Business Administration Documentation*. Agent and the Lenders acknowledge that Borrower completed, executed and delivered to Agent prior to each SBA Funding Date SBA Forms 480, 652 and 1031 (Parts A and B) together with a business plan showing Borrower's financial projections (including balance sheets and income and cash flows statements) for the period described therein and a written statement (whether included in the purchase agreement or pursuant to a separate statement) from Agent regarding its intended use of proceeds from the sale of securities to the Lenders (the "Use of Proceeds Statement"). Borrower represents and warrants to Agent and the Lenders that the information regarding Borrower and its affiliates set forth in the SBA Form 480, Form 652 and Form 1031 and the Use of Proceeds Statement delivered as of each SBA Funding Date is accurate and complete.

(c) *Inspection*. The following covenants contained in this Section (c) are intended to supplement and not to restrict the related provisions of the Loan Documents. Subject to the preceding sentence, once per year at reasonable times not disruptive to Borrower's business, Borrower will permit, for so long as the Lenders hold any debt or equity securities of Borrower, Agent, the Lenders or their representative, at Agent's or the Lenders' expense, and examiners of the SBA to visit and inspect the properties and assets of Borrower, to examine its books of account and records, and to discuss Borrower's affairs, finances and accounts with Borrower's officers, senior management and accountants, all at such reasonable times as may be requested by Agent or the Lenders or the SBA.

(d) *Annual Assessment*. Upon request of Agent or Lender, promptly after the end of each calendar year (but in any event prior to February 28 of each year) and at such other times as may be reasonably requested by Agent or the Lenders, Borrower will deliver to Agent a written assessment of the economic impact of the Lenders' investment in Borrower, specifying the full-time equivalent jobs created or retained in connection with the investment, the impact of the investment on the businesses of Borrower in terms of expanded revenue and taxes, other economic benefits resulting from the investment (such as technology development or commercialization, minority business development, or expansion of exports) and such other information as may be required regarding Borrower in connection with the filing of the Lenders' SBA Form 468. The Lenders will assist Borrower with preparing such assessment. In addition to any other rights granted hereunder, Borrower will grant Agent and the Lenders and the SBA access (during regular

business hours and upon reasonable prior notice) to Borrower's books and records for the purpose of verifying the use of such proceeds. Borrower also will furnish or cause to be furnished to Agent and the Lenders such other information regarding the business, affairs and condition of Borrower as Agent or the Lenders may from time to time reasonably request, and such information shall be certified by the President, Chief Executive Officer or Chief Financial Officer of Borrower to the extent requested by Agent or Lender for compliance with the SBIC Act.

(e) *Use of Proceeds.* Borrower will use the proceeds from the Loan only for purposes set forth in Section 7.17. Borrower will deliver to Agent from time to time promptly following Agent's request, a written report, certified as correct by Borrower's Chief Financial Officer, verifying the purposes and amounts for which proceeds from the Loan have been disbursed. Borrower will supply to Agent such additional information and documents as Agent reasonably requests with respect to its use of proceeds and will, to the extent required by Section 7.2, permit Agent and the Lenders and the SBA to have access (during regular business hours and upon reasonable prior notice) to any and all Borrower records and information and personnel as Agent deems necessary to verify how such proceeds have been or are being used, and to assure that the proceeds have been used for the purposes specified in Section 7.17.

(f) *Activities and Proceeds*. Neither Borrower nor any of its affiliates (if any) will engage in any activities or use directly or indirectly the proceeds from the Loan for any purpose for which a small business investment company is prohibited from providing funds by the SBIC Act, including 13 C.F.R. §107.720. The Borrower shall not, nor shall it cause or permit any of its subsidiaries to, without obtaining the prior written approval of Agent, change within one (1) year of the date hereof the Borrower's or any such subsidiary's business activities from that conducted on the date hereof to a business activity from which a licensee under the SBIC Act is prohibited from providing funds by the SBIC Act. The Borrower agrees that any such change in its or any such subsidiary's business activities without such prior written consent of Agent shall constitute a material breach of the obligations of the Borrower under this Addendum 2.

(g) *Redemption Provisions.* Notwithstanding any provision to the contrary contained in the Certificate of Incorporation of Borrower, as amended from time to time (the "Charter"), if, pursuant to the redemption provisions contained in the Charter, the Lenders is entitled to a redemption of its Warrant, such redemption (in the case of the Lenders) will be at a price equal to the redemption price set forth in the Charter (the "Existing Redemption Price"). If, however, the Lenders delivers written notice to Borrower that the then current regulations promulgated under the SBIC Act prohibit payment of the Existing Redemption Price in the case of an SBIC (or, if applied, the Existing Redemption Price would cause any series of preferred stock to lose its classification as an "equity security" and the Lenders has determined that such classification is unadvisable), the amount the Lenders will be entitled to receive shall be the greater of (i) fair market value of the securities being redeemed taking into account the rights and preferences of such securities plus any costs and expenses of the Lenders incurred in making or maintaining the Warrant, and (ii) the Existing Redemption Price where the amount of accrued but unpaid dividends payable to the Lenders is limited to Borrower's earnings plus any costs and expenses of the Lenders incurred in making or maintaining the Warrant; provided, however, the amount calculated in subsections (i) or (ii) above shall not exceed the Existing Redemption Price.

(h) *Compliance and Resolution.* Borrower agrees that a failure to comply with Borrower's obligations under this Addendum, or any other set of facts or circumstances where it

has been asserted by any governmental regulatory agency (or Agent or the Lenders believes that there is a substantial risk of such assertion) that Agent, the Lenders and their affiliates are not entitled to hold, or exercise any significant right with respect to, any securities issued to the Lenders by Borrower, will constitute a breach of the obligations of Borrower under the financing agreements among Borrower, Agent and the Lenders. In the event of (i) a failure to comply with Borrower's obligations under this Addendum; or (ii) an assertion by any governmental regulatory agency (or Agent or the Lenders believe that there is a substantial risk of such assertion) of a failure to comply with Borrower's obligations under this Addendum, then (i) Agent, the Lenders and Borrower will meet and resolve any such issue in good faith to the satisfaction of Borrower, Agent, the Lenders, and any governmental regulatory agency, and (ii) upon request of the Lenders or Agent, Borrower will cooperate and assist with any assignment of the financing agreements among any Lender and Hercules Capital, Inc.

ADDENDUM 3 to LOAN AND SECURITY AGREEMENT

Agent and Lender Terms

(a) Each Lender hereby irrevocably appoints Hercules Capital, Inc. to act on its behalf as the Agent hereunder and under the other Loan Documents and authorizes the Agent to take such actions on its behalf and to exercise such powers as are delegated to the Agent by the terms hereof or thereof, together with such actions and powers as are reasonably incidental thereto.

(b) Each Lender agrees to indemnify the Agent in its capacity as such (to the extent not reimbursed by Borrower and without limiting the obligation of Borrower to do so), according to its respective Term Commitment percentages (based upon the total outstanding Term Commitments) in effect on the date on which indemnification is sought under this Addendum 3, from and against any and all liabilities, obligations, losses, damages, penalties, actions, judgments, suits, costs, expenses or disbursements of any kind whatsoever that may at any time be imposed on, incurred by or asserted against the Agent in any way relating to or arising out of, this Agreement, any of the other Loan Documents or any documents contemplated by or referred to herein or therein or the transactions contemplated hereby or thereby or any action taken or omitted by the Agent under or in connection with any of the foregoing; The agreements in this Section shall survive the payment of the Loans and all other amounts payable hereunder.

(c) Agent in Its Individual Capacity. The Person serving as the Agent hereunder shall have the same rights and powers in its capacity as a Lender as any other Lender and may exercise the same as though it were not the Agent and the term "Lender" shall, unless otherwise expressly indicated or unless the context otherwise requires, include each such Person serving as Agent hereunder in its individual capacity.

(d) Exculpatory Provisions. The Agent shall have no duties or obligations except those expressly set forth herein and in the other Loan Documents. Without limiting the generality of the foregoing, the Agent shall not:

(i) be subject to any fiduciary or other implied duties, regardless of whether any Default or any Event of Default has occurred and is continuing;

(ii) have any duty to take any discretionary action or exercise any discretionary powers, except discretionary rights and powers expressly contemplated hereby or by the other Loan Documents that the Agent is required to exercise as directed in writing by the Lenders, provided that the Agent shall not be required to take any action that, in its opinion or the opinion of its counsel, may expose the Agent to liability or that is contrary to any Loan Document or applicable law; and

(iii) except as expressly set forth herein and in the other Loan Documents, have any duty to disclose, and the Agent shall not be liable for the failure to disclose, any information relating to the Borrower or any of its Affiliates that is communicated to or obtained by any Person serving as the Agent or any of its Affiliates in any capacity.

(e) The Agent shall not be liable for any action taken or not taken by it (i) with the consent or at the request of the Lenders or as the Agent shall believe in good faith shall be necessary, under the circumstances or (ii) in the absence of its own gross negligence or willful misconduct.

(f) The Agent shall not be responsible for or have any duty to ascertain or inquire into (i) any statement, warranty or representation made in or in connection with this Agreement or any other Loan Document, (ii) the contents of any certificate, report or other document delivered hereunder or thereunder or in connection herewith or therewith, (iii) the performance or observance of any of the covenants, agreements or other terms or conditions set forth herein or therein or the occurrence of any Default or Event of Default, (iv) the validity, enforceability, effectiveness or genuineness of this Agreement, any other Loan Document or any other agreement, instrument or document or (v) the satisfaction of any condition set forth in Section 4 or elsewhere herein, other than to confirm receipt of items expressly required to be delivered to the Agent.

(g) Reliance by Agent. Agent may rely, and shall be fully protected in acting, or refraining to act, upon, any resolution, statement, certificate, instrument, opinion, report, notice, request, consent, order, bond or other paper or document that it has no reason to believe to be other than genuine and to have been signed or presented by the proper party or parties or, in the case of cables, telecopies and telexes, to have been sent by the proper party or parties. In the absence of its gross negligence or willful misconduct, Agent may conclusively rely, as to the truth of the statements and the correctness of the opinions expressed therein, upon any certificates or opinions furnished to Agent and conforming to the requirements of this Agreement or any of the other Loan Documents. Agent may consult with counsel, and any opinion or legal advice of such counsel shall be full and complete authorization and protection in respect of any action taken, not taken or suffered by Agent hereunder or under any Loan Documents in accordance therewith. Agent shall have the right at any time to seek instructions concerning the administration of the Collateral from any court of competent jurisdiction. Agent shall not be under any obligation to exercise any of the rights or powers granted to Agent by this Agreement and the other Loan Documents at the request or direction of the Lenders unless Agent shall have been provided by the Lenders with adequate security and indemnity against the costs, expenses and liabilities that may be incurred by it in compliance with such request or direction.

ADDENDUM 4 to LOAN AND SECURITY AGREEMENT

Multiple Borrower Terms

(a) Borrower’s Agent. Each of the Borrowers hereby irrevocably appoints Akero Therapeutics as its agent, attorney-in-fact and legal representative for all purposes, including requesting disbursement of the Term Loan and receiving account statements and other notices and communications to Borrowers (or any of them) from the Agent or any Lender. The Agent may rely, and shall be fully protected in relying, on any request for the Term Loan Advances, disbursement instruction, report, information or any other notice or communication made or given by Akero Therapeutics, whether in its own name or on behalf of one or more of the other Borrowers, and the Agent shall not have any obligation to make any inquiry or request any confirmation from or on behalf of any other Borrower as to the binding effect on it of any such request, instruction, report, information, other notice or communication, nor shall the joint and several character of the Borrowers’ obligations hereunder be affected thereby.

(b) Waivers. Each Borrower hereby waives: (i) any right to require the Agent to institute suit against, or to exhaust its rights and remedies against, any other Borrower or any other person, or to proceed against any property of any kind which secures all or any part of the Secured Obligations, or to exercise any right of offset or other right with respect to any reserves, credits or deposit accounts held by or maintained with the Agent or any Indebtedness of the Agent or any

Lender to any other Borrower, or to exercise any other right or power, or pursue any other remedy the Agent or any Lender may have; (ii) any defense arising by reason of any disability or other defense of any other Borrower or any guarantor or any endorser, co-maker or other person, or by reason of the cessation from any cause whatsoever of any liability of any other Borrower or any guarantor or any endorser, co-maker or other person, with respect to all or any part of the Secured Obligations, or by reason of any act or omission of the Agent or others which directly or indirectly results in the discharge or release of any other Borrower or any guarantor or any other person or any Secured Obligations or any security therefor, whether by operation of law or otherwise; (iii) any defense arising by reason of any failure of the Agent to obtain, perfect, maintain or keep in force any Lien on, any property of any Borrower or any other person; (iv) any defense based upon or arising out of any bankruptcy, insolvency, reorganization, arrangement, readjustment of debt, liquidation or dissolution proceeding commenced by or against any other Borrower or any guarantor or any endorser, co-maker or other person, including without limitation any discharge of, or bar against collecting, any of the Secured Obligations (including without limitation any interest thereon), in or as a result of any such proceeding. Until all of the Secured Obligations have been paid, performed, and discharged in full, nothing shall discharge or satisfy the liability of any Borrower hereunder except the full performance and payment of all of the Secured Obligations. If any claim is ever made upon the Agent for repayment or recovery of any amount or amounts received by the Agent in payment of or on account of any of the Secured Obligations, because of any claim that any such payment constituted a preferential transfer or fraudulent conveyance, or for any other reason whatsoever, and the Agent repays all or part of said amount by reason of any judgment, decree or order of any court or administrative body having jurisdiction over the Agent or any of its property, or by reason of any settlement or compromise of any such claim effected by the Agent with any such claimant (including without limitation the any other Borrower), then and in any such event, each Borrower agrees that any such judgment, decree, order, settlement and compromise shall be binding upon such Borrower, notwithstanding any revocation or release of this Agreement or the cancellation of any note or other instrument evidencing any of the Secured Obligations, or any release of any of the Secured Obligations, and each Borrower shall be and remain liable to the Agent and the Lenders under this Agreement for the amount so repaid or recovered, to the same extent as if such amount had never originally been received by the Agent or any Lender, and the provisions of this sentence shall survive, and continue in effect, notwithstanding any revocation or release of this Agreement. Each Borrower hereby expressly and unconditionally waives all rights of subrogation, reimbursement and indemnity of every kind against any other Borrower, and all rights of recourse to any assets or property of any other Borrower, and all rights to any collateral or security held for the payment and performance of any Secured Obligations, including (but not limited to) any of the foregoing rights which Borrower may have under any present or future document or agreement with any other Borrower or other person, and including (but not limited to) any of the foregoing rights which any Borrower may have under any equitable doctrine of subrogation, implied contract, or unjust enrichment, or any other equitable or legal doctrine.

(c) Consents. Each Borrower hereby consents and agrees that, without notice to or by Borrower and without affecting or impairing in any way the obligations or liability of Borrower hereunder, the Agent may, from time to time before or after revocation of this Agreement, do any one or more of the following in its sole and absolute discretion: (i) accept partial payments of, compromise or settle, renew, extend the time for the payment, discharge, or performance of, refuse to enforce, and release all or any parties to, any or all of the Secured Obligations; (ii) grant any other indulgence to any Borrower or any other Person in respect of any or all of the Secured Obligations or any other matter; (iii) accept, release, waive, surrender, enforce, exchange, modify, impair, or extend the time for the performance, discharge, or payment of, any and all property of any kind securing any or all of the Secured Obligations or any guaranty of any or all of the Secured

Obligations, or on which the Agent at any time may have a Lien, or refuse to enforce its rights or make any compromise or settlement or agreement therefor in respect of any or all of such property; (iv) substitute or add, or take any action or omit to take any action which results in the release of, any one or more other Borrowers or any endorsers or guarantors of all or any part of the Secured Obligations, including, without limitation one or more parties to this Agreement, regardless of any destruction or impairment of any right of contribution or other right of Borrower; (v) apply any sums received from any other Borrower, any guarantor, endorser, or co-signer, or from the disposition of any Collateral or security, to any Indebtedness whatsoever owing from such person or secured by such Collateral or security, in such manner and order as the Agent determines in its sole discretion, and regardless of whether such Indebtedness is part of the Secured Obligations, is secured, or is due and payable. Each Borrower consents and agrees that the Agent shall be under no obligation to marshal any assets in favor of Borrower, or against or in payment of any or all of the Secured Obligations. Each Borrower further consents and agrees that the Agent shall have no duties or responsibilities whatsoever with respect to any property securing any or all of the Secured Obligations. Without limiting the generality of the foregoing, the Agent shall have no obligation to monitor, verify, audit, examine, or obtain or maintain any insurance with respect to, any property securing any or all of the Secured Obligations.

(d) Independent Liability. Each Borrower hereby agrees that one or more successive or concurrent actions may be brought hereon against such Borrower, in the same action in which any other Borrower may be sued or in separate actions, as often as deemed advisable by Agent. Each Borrower is fully aware of the financial condition of each other Borrower and is executing and delivering this Agreement based solely upon its own independent investigation of all matters pertinent hereto, and such Borrower is not relying in any manner upon any representation or statement of the Agent or any Lender with respect thereto. Each Borrower represents and warrants that it is in a position to obtain, and each Borrower hereby assumes full responsibility for obtaining, any additional information concerning any other Borrower’s financial condition and any other matter pertinent hereto as such Borrower may desire, and such Borrower is not relying upon or expecting the Agent to furnish to it any information now or hereafter in the Agent’s possession concerning the same or any other matter.

(e) Subordination. All Indebtedness of a Borrower now or hereafter arising held by another Borrower is subordinated to the Secured Obligations and the Borrower holding the Indebtedness shall take all actions reasonably requested by Agent to effect, to enforce and to give notice

THIS WARRANT AND THE SHARES ISSUABLE UPON EXERCISE HEREOF HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "ACT"), OR ANY STATE SECURITIES LAWS, AND MAY NOT BE SOLD, OFFERED FOR SALE, PLEDGED, OR HYPOTHECATED IN THE ABSENCE OF AN EFFECTIVE REGISTRATION STATEMENT RELATED THERETO OR, SUBJECT TO SECTION 11 HEREOF, AN OPINION OF COUNSEL (WHICH MAY BE COMPANY COUNSEL) REASONABLY SATISFACTORY TO THE COMPANY THAT SUCH REGISTRATION IS NOT REQUIRED UNDER THE ACT, OR ANY APPLICABLE STATE SECURITIES LAWS.

WARRANT AGREEMENT

To Purchase Shares of the Common Stock of

AKERO THERAPEUTICS, INC.

Dated as of June 15, 2022 (the "Effective Date")

WHEREAS, AKERO THERAPEUTICS, INC., a Delaware corporation (the " Company"), has entered into a Loan and Security Agreement of even date herewith (as amended and in effect from time to time, the "Loan Agreement") with Hercules Capital, Inc., a Maryland corporation, in its capacity as administrative and collateral agent ("Agent"), Hercules Private Global Venture Growth Fund I L.P., a Delaware limited partnership (the "Warrantholder"), and the lender parties thereto;

WHEREAS, pursuant to the Loan Agreement and as additional consideration to the Warrantholder for, among other things, its agreements in the Loan Agreement, the Company has agreed to issue to the Warrantholder this Warrant Agreement, evidencing the right to purchase shares of the Company's Common Stock (this "Warrant", "Warrant Agreement", or this "Agreement");

NOW, THEREFORE, in consideration of the Warrantholder having executed and delivered the Loan Agreement and provided the financial accommodations contemplated therein, and in consideration of the mutual covenants and agreements contained herein, the Company and the Warrantholder agree as follows:

SECTION 1.GRANT OF THE RIGHT TO PURCHASE COMMON STOCK.

(a) For value received, the Company hereby grants to the Warrantholder, and the Warrantholder is entitled, upon the terms and subject to the conditions hereinafter set forth, to subscribe for and purchase, from the Company, up to the aggregate number of fully paid and non-assessable shares of Common Stock (as defined below) as determined pursuant to Section 1(b) below, at a purchase price per share equal to the Exercise Price (as defined below). The number and Exercise Price of such shares are subject to adjustment as provided in Section 8. As used herein, the following terms shall have the following meanings:

"Act" means the Securities Act of 1933, as amended.

"Charter" means the Company's Fourth Amended and Restated Certificate of Incorporation, as may be amended and in effect from time to time.

"Common Stock" means the Company's common stock, $0.0001 par value per share, as presently constituted under the Charter, and any class and/or series of Company capital stock for or into which such common stock may be converted or exchanged in a reorganization, recapitalization or similar transaction.

"Exercise Price" means $8.17, subject to adjustment from time to time in accordance with the provisions of this Warrant.

"Liquid Sale" means the closing of a Merger Event in which the consideration received by the Company and/or its shareholders, as applicable, consists solely of cash and/or Marketable Securities.

"Marketable Securities" in connection with a Merger Event means securities meeting all of the following requirements: (i) the issuer thereof is then subject to the reporting requirements of Section 13 or Section 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and is then current in its filing of all required reports and other information under the Act and the Exchange Act; (ii) the class and series of shares or other security of the issuer that would be received by the Warrantholder in connection with the Merger Event were the Warrantholder to exercise this Warrant on or prior to the closing thereof is then traded on a national securities exchange or over-the-counter market, and (iii) following the closing of such Merger Event, the Warrantholder would not be restricted from publicly re-selling all of the issuer's shares and/or other securities that would be received by the Warrantholder in such Merger Event were the Warrantholder to exercise this Warrant in full on or prior to the closing of such Merger Event, except to the extent that any such restriction (x) arises solely under federal or state securities laws, rules or regulations, and (y) does not extend beyond six (6) months from the closing of such Merger Event.

"Merger Event" means any of the following: (i) a sale, lease or other transfer of all or substantially all assets of the Company, (ii) any merger or consolidation involving the Company in which the Company is not the surviving entity or in which the outstanding shares of the Company's capital stock are otherwise converted into or exchanged for shares of capital stock or other securities or property of another entity, or (iii) any sale by holders of the outstanding voting equity securities of the Company in a single transaction or series of related transactions of shares constituting a majority of the outstanding combined voting power of the Company.

"Purchase Price" means, with respect to any exercise of this Warrant, an amount equal to the then-effective Exercise Price multiplied by the number of shares of Common Stock as to which this Warrant is then exercised.

"Warrant Coverage" means one and one-half percent (1.50%) *multiplied* by the greater of (x) $5,000,000 and (y) the aggregate original principal amount of Term Loan Advances made by Warrantholder (as defined in the Loan Agreement)

(b) Number of Shares. This Warrant shall be exercisable for a number of shares of Common Stock equal to the quotient of (i) the Warrant Coverage, *divided* by (ii) the Exercise Price, subject to adjustment from time to time in accordance with the provisions of this Warrant.

SECTION 2.TERM OF THE AGREEMENT.

The term of this Agreement and the right to purchase Common Stock as granted herein shall commence on the Effective Date and, subject to Section 8(a) below, shall be exercisable until 5:00 p.m. (Eastern Time) on the seventh (7th) anniversary of the Effective Date.

SECTION 3.EXERCISE OF THE PURCHASE RIGHTS.

(a) Exercise. The purchase rights set forth in this Agreement are exercisable by the Warrantholder, in whole or in part, at any time, or from time to time, prior to the expiration of the term set forth in Section 2, by tendering to the Company at its principal office a notice of exercise in the form attached hereto as Exhibit I (the "Notice of Exercise"), duly completed and executed. Promptly upon receipt of the Notice of Exercise and the payment of the Purchase Price in accordance with the terms set forth below, and in no event later than three (3) business days thereafter, the Company or its transfer agent shall either (i) issue to the Warrantholder a certificate for the number of shares of Common Stock purchased or (ii) credit the same via book entry to the Warrantholder, and the Company shall execute the acknowledgment of exercise in the form attached hereto as Exhibit II (the "Acknowledgment of Exercise") indicating the number of shares which remain subject to future purchases under this Warrant, if any.

The Purchase Price may be paid at the Warrantholder's election either (i) by cash or check, or (ii) by surrender of all or a portion of the Warrant for shares of Common Stock to be exercised under this Agreement and, if applicable, an amended Agreement setting forth the remaining number of shares purchasable hereunder, as determined below ("Net Issuance"). If the Warrantholder elects the Net Issuance method, the Company will issue shares of Common Stock in accordance with the following formula:

$$X = \frac{Y(A-B)}{A}$$

Where: X = the number of shares of Common Stock to be issued to the Warrantholder.

Y = the number of shares of Common Stock requested to be exercised under this Agreement.

A = the then-current fair market value of one (1) share of Common Stock at the time of exercise of this Warrant.

B = the then-effective Exercise Price.

For purposes of the above calculation, the current fair market value of shares of Common Stock shall mean with respect to each share of Common Stock:

(i) at all times when the Common Stock is traded on a national securities exchange, inter-dealer quotation system or over-the-counter bulletin board service, the average of the closing prices over a ten (10) day consecutive period ending three days before the day the current fair market value of the securities is being determined;

(ii) if the exercise is in connection with a Merger Event, the fair market value of a share of Common Stock shall be deemed to be the per share value received by the holders of the outstanding shares of Common Stock pursuant to such Merger Event as determined in accordance with the definitive transaction documents executed among the parties in connection therewith; or

(iii) in cases other than as described in the foregoing clauses (i) and (ii), the current fair market value of a share of Common Stock shall be determined in good faith by the Company's Board of Directors.

Upon partial exercise by either cash or Net Issuance, prior to the expiration or earlier termination hereof, the Company shall promptly issue an amended Agreement representing the remaining number of shares purchasable hereunder. All other terms and conditions of such amended Agreement shall be identical to those contained herein, including, but not limited to the Effective Date hereof.

(b) Exercise Prior to Expiration. To the extent this Warrant is not previously exercised as to all shares of Common Stock subject hereto, and if the then-current fair market value of one share of Common Stock is greater than the Exercise Price then in effect, or, in the case of a Liquid Sale, where the value per share of Common Stock (as determined as of the closing of such Liquid Sale in accordance with the definitive agreements executed by the parties in connection with such Merger Event) to be paid to the holders thereof is greater than the Exercise Price then in effect, this Agreement shall be deemed automatically exercised on a Net Issuance basis pursuant to Section 3(a) (even if not surrendered) as of immediately before its expiration determined in accordance with Section 2. For purposes of such automatic exercise, the fair market value of one share of Common Stock upon such expiration shall be determined pursuant to Section 3(a). To the extent this Warrant or any portion hereof is deemed automatically exercised pursuant to this Section 3(b), the Company agrees to promptly notify the Warrantholder of the number of shares of Common Stock if any, the Warrantholder is to receive by reason of such automatic exercise, and to issue or cause its transfer agent to issue a certificate or a book-entry credit to the Warrantholder evidencing such shares.

SECTION 4.RESERVATION OF SHARES.

During the term of this Agreement, the Company will at all times have authorized and reserved a sufficient number of shares of its Common Stock to provide for the exercise of the rights to purchase Common Stock as provided for herein. If at any time during the term hereof the number of authorized but unissued shares of Common Stock shall not be sufficient to permit exercise of this Warrant in full, the Company will take such corporate action as may, in the opinion of its counsel, be necessary to increase its authorized but unissued shares of Common Stock to such number of shares as shall be sufficient for such purposes.

SECTION 5.NO FRACTIONAL SHARES OR SCRIP.

No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Agreement, but in lieu of such fractional shares the Company shall make a cash payment therefor in an amount equal to the product of (a) the Exercise Price then in effect multiplied by (b) the fraction of a share.

SECTION 6.NO RIGHTS AS SHAREHOLDER.

Without limitation of any provision hereof, the Warrantholder agrees that this Agreement does not entitle the Warrantholder to any voting rights or other rights as a shareholder of the Company prior to the exercise of any of the purchase rights set forth in this Agreement.

SECTION 7.WARRANTHOLDER REGISTRY.

The Company shall maintain a registry showing the name and address of the registered holder of this Agreement. The Warrantholder's initial address, for purposes of such registry, is set forth in Section 12(g) below. The Warrantholder may change such address by giving written notice of such changed address to the Company.

SECTION 8.ADJUSTMENT RIGHTS.

The Exercise Price and the number of shares of Common Stock purchasable hereunder are subject to adjustment from time to time, as follows:

(a) Merger Event. In connection with a Merger Event that is a Liquid Sale, this Warrant shall, on and after the closing thereof, automatically and without further action on the part of any party or other person, represent the right to receive the consideration payable on or in respect of all shares of Common Stock that are issuable hereunder as of immediately prior to the closing of such Merger Event less the Purchase Price for all such shares of Common Stock (such consideration to include both the

consideration payable at the closing of such Merger Event and all deferred consideration payable thereafter, if any, including, but not limited to, payments of amounts deposited at such closing into escrow and payments in the nature of earn-outs, milestone payments or other performance-based payments), and such Merger Event consideration shall be paid to the Warrantholder as and when it is paid to the holders of the outstanding shares of Common Stock. In connection with a Merger Event that is not a Liquid Sale, the Company shall cause the successor or surviving entity to assume this Warrant and the obligations of the Company hereunder on the closing thereof, and thereafter this Warrant shall be exercisable for the same number and type of securities or other property as the Warrantholder would have received in consideration for the shares of Common Stock issuable hereunder had it exercised this Warrant in full as of immediately prior to such closing, at an aggregate Exercise Price no greater than the aggregate Exercise Price in effect as of immediately prior to such closing, and subject to further adjustment from time to time in accordance with the provisions of this Warrant. The provisions of this Section 8(a) shall similarly apply to successive Merger Events.

(b) Reclassification of Shares. Except for Merger Events subject to Section 8(a), if the Company at any time shall, by combination, reclassification, exchange or subdivision of securities or otherwise, change any of the securities as to which purchase rights under this Agreement exist into the same or a different number of securities of any other class or classes of securities, this Agreement shall thereafter represent the right to acquire such number and kind of securities as would have been issuable as the result of such change with respect to the securities which were subject to the purchase rights under this Agreement immediately prior to such combination, reclassification, exchange, subdivision or other change. The provisions of this Section 8(b) shall similarly apply to successive combination, reclassification, exchange, subdivision or other change.

(c) Subdivision or Combination of Shares. If the Company at any time shall combine or subdivide its Common Stock, (i) in the case of a subdivision, the Exercise Price shall be proportionately decreased and the number of shares for which this Warrant is exercisable shall be proportionately increased, or (ii) in the case of a combination, the Exercise Price shall be proportionately increased and the number of shares for which this Warrant is exercisable shall be proportionately decreased.

(d) Dividends. If the Company at any time while this Agreement is outstanding and unexpired shall:

(i) pay a dividend with respect to the outstanding shares of Common Stock payable in additional shares of Common Stock, then the Exercise Price shall be adjusted, from and after the date of determination of shareholders entitled to receive such dividend, to that price determined by multiplying the Exercise Price in effect immediately prior to such date of determination by a fraction (A) the numerator of which shall be the total number of shares of Common Stock outstanding immediately prior to such dividend or distribution, and (B) the denominator of which shall be the total number of shares of Common Stock outstanding immediately after such dividend or distribution, and the number of shares of Common Stock for which this Warrant is exercisable shall be proportionately increased; or

(ii) make any other dividend or distribution on or with respect to Common Stock, except any dividend or distribution (A) in cash, or (B) specifically provided for in any other clause of this Section 8, then, in each such case, provision shall be made by the Company such that the Warrantholder shall receive upon exercise or conversion of this Warrant a proportionate share of any such dividend or distribution as though it were the holder of the Common Stock (or other stock for which the Common Stock is convertible) as of the record date fixed for the determination of the shareholders of the Company entitled to receive such dividend or distribution.

(e) Notice of Certain Events. If: (i) the Company shall declare any dividend or distribution upon its outstanding Common Stock, payable in stock, cash, property or other securities (provided that the Warrantholder in its capacity as lender under the Loan Agreement consents to such dividend); (ii) the Company shall offer for subscription pro rata to the holders of its Common Stock any additional shares of stock of any class or other rights; (iii) there shall be any Merger Event; or (iv) there shall be any voluntary dissolution, liquidation or winding up of the Company; then, in connection with each such event, the Company shall give the Warrantholder notice thereof at the same time and in the same manner as it gives notice thereof to the holders of outstanding Common Stock. In addition, if at any time the number of shares of Common Stock (or other securities of any other class or classes of securities of the Company for which this Warrant is then exercisable) outstanding is reduced such that the number of shares of Common Stock or other securities issuable upon exercise of this Warrant shall exceed five percent (5%) of the then outstanding class of such securities, then, within three (3) business days of such event, the Company shall give the Warrantholder written notice thereof.

SECTION 9.REPRESENTATIONS, WARRANTIES AND COVENANTS OF THE COMPANY.

(a) Reservation of Common Stock. The Company covenants and agrees that all shares of Common Stock that may be issued upon the exercise of the rights represented by this Warrant will, upon issuance, be validly issued and outstanding, fully paid and non-assessable, and will be free of any taxes, liens, charges or encumbrances of any nature whatsoever; provided, that the Common Stock issuable pursuant to this Agreement may be subject to restrictions on transfer under state and/or federal securities laws. The Company has made available to the Warrantholder true, correct and complete copies of its Charter and bylaws currently in effect. The issuance of certificates or book-entry credit for shares of Common Stock upon exercise of this Warrant shall be made without charge to the Warrantholder for any issuance tax in respect thereof, or other cost incurred by the Company in connection with such exercise and related issuance of shares of Common Stock. The Company further covenants and agrees that the Company will, at all times during the term hereof, have authorized and reserved, free from preemptive rights, a sufficient number of shares of Common Stock to provide for the exercise of the rights represented by this Warrant.

(b) Due Authority. The execution and delivery by the Company of this Agreement and the performance of all obligations of the Company hereunder, including the issuance to the Warrantholder of the right to acquire the shares of Common Stock, have been duly authorized by all necessary corporate action on the part of the Company. This Agreement: (i) does not violate the Charter or the Company's current bylaws; (ii) does not contravene any law or governmental rule, regulation or order applicable to the Company; and (iii) except as could not reasonably be expected to have a Material Adverse Effect (as defined in the Loan Agreement), does not and will not contravene any provision of, or constitute a default under, any indenture, mortgage, contract or other instrument to which the Company is a party or by which it is bound. This Agreement constitutes a legal, valid and binding agreement of the Company, enforceable in accordance with its terms, except as may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws relating to or affecting creditors' rights generally (including, without limitation, fraudulent conveyance laws) and by general principles of equity, regardless of whether considered in a proceeding in equity or at law.

(c) Consents and Approvals. No consent or approval of, giving of notice to, registration with, or taking of any other action in respect of any state, federal or other governmental authority or agency is required with respect to the execution, delivery and performance by the Company of its obligations under this Agreement, except for the filing of notices pursuant to Regulation D under the Act and any filing required by applicable state securities law, which filings will be effective by the time required thereby.

(d) Exempt Transaction. Subject to the accuracy of the Warrantholder's representations in Section 10, the issuance of the Common Stock upon exercise of this Agreement will constitute a transaction exempt

from (i) the registration requirements of Section 5 of the Act, in reliance upon Section 4(a)(2) thereof, and (ii) the qualification requirements of the applicable state securities laws.

(e) Information Rights. At all times (if any) prior to the earlier to occur of (i) the date on which all shares of Common Stock issued on exercise of this Warrant have been sold, or (ii) the expiration or earlier termination of this Warrant, when the Company shall not be required to file reports pursuant to Section 13 or 15(d) of the Exchange Act or shall not have timely filed all such required reports, the Warrantholder shall be entitled to the information rights contained in Section 7.1(b) of the Loan Agreement, provided that the confidentiality provisions contained in Section 11.13 of the Loan Agreement shall apply to any information received under this section, and in any such event Section 7.1(b) and Section 11.13 of the Loan Agreement is hereby incorporated into this Agreement by this reference as though fully set forth herein, provided, however, that the Company shall not be required to deliver a Compliance Certificate once all Indebtedness (as defined in the Loan Agreement) owed by the Company to the Warrantholder has been repaid.

(a) Rule 144 Compliance. The Company shall, at all times prior to the earlier to occur of (i) the date of sale or other disposition by the Warrantholder of this Warrant or all shares of Common Stock issued on exercise of this Warrant, or (ii) the expiration or earlier termination of this Warrant if the Warrant has not been exercised in full or in part on such date, use all commercially reasonable efforts to timely file all reports required under the Exchange Act and otherwise timely take all actions necessary to permit the Warrantholder to sell or otherwise dispose of this Warrant and the shares of Common Stock issued on exercise hereof pursuant to Rule 144 promulgated under the Act ("Rule 144"), provided that the foregoing shall not apply in the event of a Merger Event following which the successor or surviving entity is not subject to the reporting requirements of the Exchange Act. If the Warrantholder proposes to sell Common Stock issuable upon the exercise of this Agreement in compliance with Rule 144, then, upon the Warrantholder's written request to the Company, the Company shall furnish to the Warrantholder, within five (5) business days after receipt of such request, a written statement confirming the Company's compliance with the filing and other requirements of such Rule 144.

(b) Registration of Shares. Within six (6) months following the exercise of this Warrant, the Company shall prepare and file with the Securities and Exchange Commission a registration statement covering the resale of the shares issued pursuant to such Exercise Notice for an offering to be made on a continuous basis and shall use best efforts to cause such registration statement to be declared effective. Notwithstanding the foregoing, the Company shall not be required to comply with this Section 9(g) in the event that the shares issued pursuant to the exercise of this warrant may be sold under Rule 144 or another similar exemption under the Securities Act.

SECTION 10.REPRESENTATIONS AND COVENANTS OF THE WARRANTHOLDER.

This Agreement has been entered into by the Company in reliance upon the following representations and covenants of the Warrantholder:

(a) Investment Purpose. This Warrant and the shares issued on exercise hereof will be acquired for investment and not with a view to the sale or distribution of any part thereof in violation of applicable federal and state securities laws, and the Warrantholder has no present intention of selling or engaging in any public distribution of the same except pursuant to a registration or exemption.

(b) Private Issue. The Warrantholder understands that (i) the Common Stock issuable upon exercise of this Agreement is not, as of the Effective Date, registered under the Act or qualified under applicable state securities laws on the grounds that the issuance contemplated by this Agreement will be exempt from the registration and qualifications requirements thereof, and (ii) the Company's reliance on exemption from such registration is predicated on the representations set forth in this Section 10.

(c) Financial Risk. The Warrantholder has such knowledge and experience in financial and business matters as to be capable of evaluating the merits and risks of its investment, and has the ability to bear the economic risks of its investment.

(d) Accredited Investor. The Warrantholder is an "accredited investor" within the meaning of Rule 501 of Regulation D promulgated under the Act, as presently in effect ("Regulation D").

(e) No Short Sales. The Warrantholder has not at any time on or prior to the Effective Date engaged in any short sales or equivalent transactions in the Common Stock. Warrantholder agrees that at all times from and after the Effective Date and on or before the expiration or earlier termination of this Warrant, it shall not engage in any short sales or equivalent transactions in the Common Stock.

SECTION 11.TRANSFERS.

Subject to compliance with applicable federal and state securities laws, this Agreement and all rights hereunder are transferable, in whole or in part, without charge to the holder hereof (except for transfer taxes) upon surrender of this Agreement properly endorsed, provided, that as long as no Event of Default (as defined in the Loan Agreement) has occurred and is continuing, the holder hereof may not, without the Company's prior written consent, transfer this Agreement or any portion hereof, or any shares issued upon any exercise hereof, to any person or entity who directly competes with the Company (as reasonably determined by Agent upon consultation with Company), it being acknowledged that in all cases, any transfer to an affiliate of the holder hereof shall be allowed. Each taker and holder of this Agreement, by taking or holding the same, consents and agrees that this Agreement, when endorsed in blank, shall be deemed negotiable, and that the holder hereof, when this Agreement shall have been so endorsed and its transfer recorded on the Company's books, shall be treated by the Company and all other persons dealing with this Agreement as the absolute owner hereof for any purpose and as the person entitled to exercise the rights represented by this Agreement. Subject to the first sentence of this Section 11, the transfer of this Agreement shall be recorded on the books of the Company upon receipt by the Company of a notice of transfer in the form attached hereto as Exhibit III (the "Transfer Notice"), at its principal offices and the payment to the Company of all transfer taxes and other governmental charges imposed on such transfer. Until the Company receives such Transfer Notice, the Company may treat the registered owner hereof as the owner for all purposes. Notwithstanding anything herein or in any legend to the contrary, the Company shall not require an opinion of counsel in connection with any sale, assignment or other transfer by the Warrantholder of this Warrant (or any portion hereof or any interest herein) or of any shares of Common Stock issued upon any exercise hereof to an affiliate (as defined in Regulation D) of the Warrantholder, provided that such affiliate is an "accredited investor" as defined in Regulation D.

SECTION 12.MISCELLANEOUS.

(a) Effective Date. The provisions of this Agreement shall be construed and shall be given effect in all respects as if it had been executed and delivered by the Company on the date hereof. This Agreement shall be binding upon any successors or assigns of the Company.

(b) Remedies. In the event of any default hereunder, the non-defaulting party may proceed to protect and enforce its rights either by suit in equity and/or by action at law, including but not limited to an action for damages as a result of any such default, and/or an action for specific performance for any default where the Warrantholder will not have an adequate remedy at law and where damages will not be readily ascertainable.

(c) No Impairment of Rights. The Company will not, by amendment of its Charter or through any other means, avoid or seek to avoid the observance or performance of any of the terms of this Agreement, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be reasonably necessary or appropriate in order to protect the rights of the Warrantholder against impairment.

(d) Additional Documents. In the event the Company shall not be required to file reports pursuant to Section 13 or 15(d) of the Exchange Act, the Company agrees to supply such other documents as the Warrantholder may from time to time reasonably request to value this Warrant for Warrantholder's accounting or reporting requirements and/or to evaluate whether to exercise (in cash or a net issuance basis) this Warrant.

(e) Attorneys' Fees. In any litigation, arbitration or court proceeding between the Company and the Warrantholder relating hereto, the prevailing party shall be entitled to reasonable and documented attorneys' fees and expenses and all costs of proceedings incurred in enforcing this Agreement. For the purposes of this Section 12(e), attorneys' fees shall include without limitation fees incurred in connection with the following: (i) contempt proceedings; (ii) discovery; (iii) any motion, proceeding or other activity of any kind in connection with an insolvency proceeding; (iv) garnishment, levy, and debtor and third party examinations; and (v) post-judgment motions and proceedings of any kind, including without limitation any activity taken to collect or enforce any judgment.

(f) Severability. In the event any one or more of the provisions of this Agreement shall for any reason be held invalid, illegal or unenforceable, the remaining provisions of this Agreement shall be unimpaired, and the invalid, illegal or unenforceable provision shall be replaced by a mutually acceptable valid, legal and enforceable provision, which comes closest to the intention of the parties underlying the invalid, illegal or unenforceable provision.

(g) Notices. Except as otherwise provided herein, any notice, demand, request, consent, approval, declaration, service of process or other communication that is required, contemplated, or permitted under this Agreement or with respect to the subject matter hereof shall be in writing, and shall be deemed to have been validly served, given, delivered, and received upon the earlier of: (i) personal delivery to the party to be notified, (ii) when sent by confirmed telex or electronic transmission if sent during normal business hours of the recipient, if not, then on the next business day, (iii) five (5) days after having been sent by registered or certified mail, return receipt requested, postage prepaid, or (iv) one day after deposit with a nationally recognized overnight courier, specifying next day delivery, with written verification of receipt, and shall be addressed to the party to be notified as follows:

If to the Warrantholder:

HERCULES PRIVATE GLOBAL VENTURE GROWTH FUND I L.P.
Legal Department
Attention: Chief Legal Officer, Cristy Barnes, Himani Bhalla and Briana Gironda
400 Hamilton Avenue, Suite 310
Palo Alto, CA 94301
Facsimile: [Redacted]
Telephone: [Redacted]

With a copy to (which shall not constitute notice):

DLA PIPER LLP (US)
401 B Street, Suite 1700
San Diego, California 92101-4297
Attn: Matt Schwartz, Esq.
Facsimile: [Redacted]
Telephone: [Redacted]

If to the Company:

AKERO THERAPEUTICS, INC.
Attention: Jonathan M. Young; William White
601 Gateway Blvd, Suite 350

South San Francisco, CA 94080
email: [Redacted]

With a copy to (which shall not constitute notice):

GOODWIN PROCTER LLP
100 Northern Avenue

Boston, MA 02210
Attention: Mark D. Smith, Esq.

Facsimile: [Redacted]
Telephone: [Redacted]

or to such other address as each party may designate for itself by like notice.

(h) Entire Agreement; Amendments. This Agreement constitutes the entire agreement and understanding of the parties hereto in respect of the subject matter hereof, and supersedes and replaces in their entirety any prior proposals, term sheets, letters, negotiations or other documents or agreements, whether written or oral, with respect to the subject matter hereof. None of the terms of this Agreement may be amended except by an instrument executed by each of the parties hereto.

(i) Headings. The various headings in this Agreement are inserted for convenience only and shall not affect the meaning or interpretation of this Agreement or any provisions hereof.

(j) Advice of Counsel. Each of the parties represents to each other party hereto that it has discussed (or had an opportunity to discuss) with its counsel this Agreement and, specifically, the provisions of Sections 12(n), 12(o), 12(p), 12(q) and 12(r).

(k) No Strict Construction. The parties hereto have participated jointly in the negotiation and drafting of this Agreement. In the event an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as if drafted jointly by the parties hereto and no presumption or burden of proof shall arise favoring or disfavoring any party by virtue of the authorship of any provisions of this Agreement.

(l) No Waiver. No omission or delay by the Warrantholder at any time to enforce any right or remedy reserved to it, or to require performance of any of the terms, covenants or provisions hereof by the Company at any time designated, shall be a waiver of any such right or remedy to which the Warrantholder is entitled, nor shall it in any way affect the right of the Warrantholder to enforce such provisions thereafter during the term of this Agreement.

(m) Survival. All agreements, representations and warranties contained in this Agreement or in any document delivered pursuant hereto shall be for the benefit of the Warrantholder and shall survive the execution and delivery of this Agreement and the expiration or other termination of this Agreement.

(n) Governing Law. This Agreement has been negotiated and delivered to the Warrantholder in the State of California, and shall be deemed to have been accepted by the Warrantholder in the State of California. Delivery of Common Stock to the Warrantholder by the Company under this Agreement is due in the State of California. This Agreement shall be governed by, and construed and enforced in accordance with, the laws of the State of California, excluding conflict of laws principles that would cause the application of laws of any other jurisdiction.

(o) Consent to Jurisdiction and Venue. All judicial proceedings arising in or under or related to this Agreement may be brought in any state or federal court of competent jurisdiction located in the State of California. By execution and delivery of this Agreement, each party hereto generally and unconditionally: (i) consents to personal jurisdiction in Santa Clara County, State of California; (ii) waives any objection as to jurisdiction or venue in Santa Clara County, State of California; (iii) agrees not to assert any defense based on lack of jurisdiction or venue in the aforesaid courts; and (iv) irrevocably agrees to be bound by any judgment rendered thereby in connection with this Agreement. Service of process on any party hereto in any action arising out of or relating to this Agreement shall be effective if given in accordance with the requirements for notice set forth in Section 12(g), and shall be deemed effective and received as set forth in Section 12(g). Nothing herein shall affect the right to serve process in any other manner permitted by law or shall limit the right of either party to bring proceedings in the courts of any other jurisdiction.

(p) Mutual Waiver of Jury Trial. Because disputes arising in connection with complex financial transactions are most quickly and economically resolved by an experienced and expert person and the parties wish applicable state and federal laws to apply (rather than arbitration rules), the parties desire that their disputes arising under or in connection with this Warrant be resolved by a judge applying such applicable laws. EACH OF THE COMPANY AND THE WARRANTHOLDER SPECIFICALLY WAIVES ANY RIGHT IT MAY HAVE TO TRIAL BY JURY OF ANY CAUSE OF ACTION, CLAIM, CROSS-CLAIM, COUNTERCLAIM, THIRD PARTY CLAIM OR ANY OTHER CLAIM (COLLECTIVELY, "CLAIMS") ASSERTED BY THE COMPANY AGAINST THE WARRANTHOLDER OR ITS ASSIGNEE OR BY THE WARRANTHOLDER OR ITS ASSIGNEE AGAINST THE COMPANY RELATING TO THIS WARRANT. This waiver extends to all such Claims, including Claims that involve persons or entities other the Company and the Warrantholder; Claims that arise out of or are in any way connected to the relationship between the Company and the Warrantholder; and any Claims for damages, breach of contract, specific performance, or any equitable or legal relief of any kind, arising out of this Agreement.

(q) Arbitration. If the Mutual Waiver of Jury Trial set forth in Section 12(p) is ineffective or unenforceable, the parties agree that all Claims shall be submitted to binding arbitration in accordance with the commercial arbitration rules of JAMS (the "Rules"), such arbitration to occur before one arbitrator, which arbitrator shall be a retired California state judge or a retired Federal court judge. Such proceeding shall be conducted in Santa Clara County, State of California, with California rules of evidence and discovery applicable to such arbitration. The decision of the arbitrator shall be binding on the parties, and shall be final and nonappealable to the maximum extent permitted by law. Any judgment rendered by the arbitrator may be entered in a court of competent jurisdiction and enforced by the prevailing party as a final judgment of such court.

(r) Pre-arbitration Relief. In the event Claims are to be resolved by arbitration, either party may seek from a court of competent jurisdiction identified in Section 12(o), any prejudgment order, writ or other relief and have such prejudgment order, writ or other relief enforced to the fullest extent permitted by law notwithstanding that all Claims are otherwise subject to resolution by binding arbitration.

(s) Counterparts. This Agreement and any amendments, waivers, consents or supplements hereto may be executed in any number of counterparts (including by facsimile or electronic delivery (PDF), and by different parties hereto in separate counterparts, each of which when so delivered shall be deemed an original, but all of which counterparts shall constitute but one and the same instrument.

(t) Specific Performance. The parties hereto hereby declare that it is impossible to measure in money the damages which will accrue to the Warrantholder by reason of the Company's failure to perform any of the obligations under this Agreement and agree that the terms of this Agreement shall be specifically enforceable by the Warrantholder. If the Warrantholder institutes any action or proceeding to specifically enforce the provisions hereof, any person against whom such action or proceeding is brought hereby waives

the claim or defense therein that the Warrantholder has an adequate remedy at law, and such person shall not offer in any such action or proceeding the claim or defense that such remedy at law exists.

(u) Lost, Stolen, Mutilated or Destroyed Warrant. If this Warrant is lost, stolen, mutilated or destroyed, the Company may, on such terms as to indemnity or otherwise as it may reasonably impose (which shall, in the case of a mutilated Warrant, include the surrender thereof), issue a new Warrant of like denomination and tenor as this Warrant so lost, stolen, mutilated or destroyed. Any such new Warrant shall constitute an original contractual obligation of the Company, whether or not the allegedly lost, stolen, mutilated or destroyed Warrant shall be at any time enforceable by anyone.

(v) Legends. To the extent required by applicable laws, this Warrant and the shares of Common Stock issuable hereunder (and the securities issuable, directly or indirectly, upon conversion of such shares of Common Stock, if any) may be imprinted with a restricted securities legend in substantially the following form:

THIS SECURITY HAS NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "ACT"), OR ANY APPLICABLE STATE SECURITIES LAWS, AND MAY NOT BE SOLD, OFFERED FOR SALE, PLEDGED OR HYPOTHECATED IN THE ABSENCE OF AN EFFECTIVE REGISTRATION RELATED THERETO OR, SUBJECT TO SECTION 11 OF THE WARRANT AGREEMENT DATED JUNE 15, 2022, BETWEEN THE COMPANY AND HERCULES PRIVATE GLOBAL VENTURE GROWTH FUND I L.P., AN OPINION OF COUNSEL (WHICH MAY BE COMPANY COUNSEL) REASONABLY SATISFACTORY TO THE COMPANY THAT SUCH REGISTRATION IS NOT REQUIRED UNDER THE ACTOR ANY STATE SECURITIES LAWS.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the parties hereto have caused this Warrant Agreement to be executed by its officers thereunto duly authorized as of the Effective Date.

COMPANY:

AKERO THERAPEUTICS, INC.

By: /s/ Andrew Cheng
Name: Andrew Cheng
Title: President and Chief Executive Officer

WARRANTHOLDER:

HERCULES PRIVATE GLOBAL VENTURE GROWTH FUND I L.P.

By: Hercules Adviser LLC, its Investment Adviser

Signature: /s/ Seth Meyer
Print Name: Seth Meyer
Title: Authorized Signatory

EXHIBIT I

NOTICE OF EXERCISE

To: AKERO THERAPEUTICS, INC.

(1) The undersigned Warrantholder hereby elects to purchase [_____] shares of the Common Stock of AKERO THERAPEUTICS, INC., pursuant to the terms of the Warrant Agreement dated the 15th day of June, 2022 (the "Warrant Agreement") between AKERO THERAPEUTICS, INC. and the Warrantholder, and [CASH PAYMENT: tenders herewith payment of the Purchase Price in full, together with all applicable transfer taxes, if any.] [NET ISSUANCE: elects pursuant to Section 3(a) of the Warrant Agreement to effect a Net Issuance.]

(2) Please issue a certificate or certificates or book-entry credit(s) representing said shares of Common Stock in the name of the undersigned or in such other name as is specified below.

_____
(Name)

_____
(Address)

WARRANTHOLDER: HERCULES PRIVATE GLOBAL VENTURE GROWTH FUND I L.P.

By: Hercules Adviser LLC, its Investment Adviser

By: _____
Name: _____
Title: _____

EXHIBIT II

1. ACKNOWLEDGMENT OF EXERCISE

The undersigned, AKERO THERAPEUTICS, INC., hereby acknowledges receipt of the "Notice of Exercise" from HERCULES PRIVATE GLOBAL VENTURE GROWTH FUND I L.P. to purchase [____] shares of the Common Stock of AKERO THERAPEUTICS, INC. pursuant to the terms of the Warrant Agreement by and between AKERO THERAPEUTICS, INC. and HERCULES PRIVATE GLOBAL VENTURE GROWTH FUND I L.P. dated the 15th day of June, 2022 (the "Warrant Agreement"), and further acknowledges that [_____] shares remain subject to purchase under the terms of the Warrant Agreement.

COMPANY: AKERO THERAPEUTICS, INC.

By: _____

Title: _____

Date: _____

EXHIBIT III

TRANSFER NOTICE

(To transfer or assign the foregoing Agreement execute this form and supply required information. Do not use this form to purchase shares.)

FOR VALUE RECEIVED, the foregoing Agreement and all rights evidenced thereby are hereby transferred and assigned to

_____
(Please Print)

whose address is_____

_____

Dated: _____

Holder's Signature: _____

Holder's Address: _____

_____

Signature Guaranteed: _____

NOTE: The signature to this Transfer Notice must correspond with the name as it appears on the face of the Agreement, without alteration or enlargement or any change whatever. Officers of corporations and those acting in a fiduciary or other representative capacity should file proper evidence of authority to assign the foregoing Agreement.

THIS WARRANT AND THE SHARES ISSUABLE UPON EXERCISE HEREOF HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "ACT"), OR ANY STATE SECURITIES LAWS, AND MAY NOT BE SOLD, OFFERED FOR SALE, PLEDGED, OR HYPOTHECATED IN THE ABSENCE OF AN EFFECTIVE REGISTRATION STATEMENT RELATED THERETO OR, SUBJECT TO SECTION 11 HEREOF, AN OPINION OF COUNSEL (WHICH MAY BE COMPANY COUNSEL) REASONABLY SATISFACTORY TO THE COMPANY THAT SUCH REGISTRATION IS NOT REQUIRED UNDER THE ACT, OR ANY APPLICABLE STATE SECURITIES LAWS.

WARRANT AGREEMENT

To Purchase Shares of the Common Stock of

AKERO THERAPEUTICS, INC.

Dated as of June 15, 2022 (the "Effective Date")

WHEREAS, AKERO THERAPEUTICS, INC., a Delaware corporation (the " Company"), has entered into a Loan and Security Agreement of even date herewith (as amended and in effect from time to time, the "Loan Agreement") with Hercules Capital, Inc., a Maryland corporation, in its capacity as administrative and collateral agent ("Agent"), Hercules Capital, Inc., a Maryland corporation (the "Warrantholder"), and the lender parties thereto;

WHEREAS, pursuant to the Loan Agreement and as additional consideration to the Warrantholder for, among other things, its agreements in the Loan Agreement, the Company has agreed to issue to the Warrantholder this Warrant Agreement, evidencing the right to purchase shares of the Company's Common Stock (this "Warrant", "Warrant Agreement", or this "Agreement");

NOW, THEREFORE, in consideration of the Warrantholder having executed and delivered the Loan Agreement and provided the financial accommodations contemplated therein, and in consideration of the mutual covenants and agreements contained herein, the Company and the Warrantholder agree as follows:

SECTION 1.GRANT OF THE RIGHT TO PURCHASE COMMON STOCK.

(a) For value received, the Company hereby grants to the Warrantholder, and the Warrantholder is entitled, upon the terms and subject to the conditions hereinafter set forth, to subscribe for and purchase, from the Company, up to the aggregate number of fully paid and non-assessable shares of Common Stock (as defined below) as determined pursuant to Section 1(b) below, at a purchase price per share equal to the Exercise Price (as defined below). The number and Exercise Price of such shares are subject to adjustment as provided in Section 8. As used herein, the following terms shall have the following meanings:

"Act" means the Securities Act of 1933, as amended.

"Charter" means the Company's Fourth Amended and Restated Certificate of Incorporation, as may be amended and in effect from time to time.

"Common Stock" means the Company's common stock, $0.0001 par value per share, as presently constituted under the Charter, and any class and/or series of Company capital stock for or into which such common stock may be converted or exchanged in a reorganization, recapitalization or similar transaction.

"Exercise Price" means $8.17, subject to adjustment from time to time in accordance with the provisions of this Warrant.

"Liquid Sale" means the closing of a Merger Event in which the consideration received by the Company and/or its shareholders, as applicable, consists solely of cash and/or Marketable Securities.

"Marketable Securities" in connection with a Merger Event means securities meeting all of the following requirements: (i) the issuer thereof is then subject to the reporting requirements of Section 13 or Section 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and is then current in its filing of all required reports and other information under the Act and the Exchange Act; (ii) the class and series of shares or other security of the issuer that would be received by the Warrantholder in connection with the Merger Event were the Warrantholder to exercise this Warrant on or prior to the closing thereof is then traded on a national securities exchange or over-the-counter market, and (iii) following the closing of such Merger Event, the Warrantholder would not be restricted from publicly re-selling all of the issuer's shares and/or other securities that would be received by the Warrantholder in such Merger Event were the Warrantholder to exercise this Warrant in full on or prior to the closing of such Merger Event, except to the extent that any such restriction (x) arises solely under federal or state securities laws, rules or regulations, and (y) does not extend beyond six (6) months from the closing of such Merger Event.

"Merger Event" means any of the following: (i) a sale, lease or other transfer of all or substantially all assets of the Company, (ii) any merger or consolidation involving the Company in which the Company is not the surviving entity or in which the outstanding shares of the Company's capital stock are otherwise converted into or exchanged for shares of capital stock or other securities or property of another entity, or (iii) any sale by holders of the outstanding voting equity securities of the Company in a single transaction or series of related transactions of shares constituting a majority of the outstanding combined voting power of the Company.

"Purchase Price" means, with respect to any exercise of this Warrant, an amount equal to the then-effective Exercise Price multiplied by the number of shares of Common Stock as to which this Warrant is then exercised.

"Warrant Coverage" means one and one-half percent (1.50%) *multiplied* by the greater of (x) $15,000,000 and (y) the aggregate original principal amount of Term Loan Advances made by Warrantholder (as defined in the Loan Agreement)

(b) Number of Shares. This Warrant shall be exercisable for a number of shares of Common Stock equal to the quotient of (i) the Warrant Coverage, *divided* by (ii) the Exercise Price, subject to adjustment from time to time in accordance with the provisions of this Warrant.

SECTION 2.TERM OF THE AGREEMENT.

The term of this Agreement and the right to purchase Common Stock as granted herein shall commence on the Effective Date and, subject to Section 8(a) below, shall be exercisable until 5:00 p.m. (Eastern Time) on the seventh (7th) anniversary of the Effective Date.

SECTION 3.EXERCISE OF THE PURCHASE RIGHTS.

(a) Exercise. The purchase rights set forth in this Agreement are exercisable by the Warrantholder, in whole or in part, at any time, or from time to time, prior to the expiration of the term set forth in Section 2, by tendering to the Company at its principal office a notice of exercise in the form attached hereto as Exhibit I (the "Notice of Exercise"), duly completed and executed. Promptly upon receipt of the Notice of Exercise and the payment of the Purchase Price in accordance with the terms set forth below, and in no event later than three (3) business days thereafter, the Company or its transfer agent shall either (i) issue to the Warrantholder a certificate for the number of shares of Common Stock purchased or (ii) credit the same via book entry to the Warrantholder, and the Company shall execute the acknowledgment of exercise in the form attached hereto as Exhibit II (the "Acknowledgment of Exercise") indicating the number of shares which remain subject to future purchases under this Warrant, if any.

The Purchase Price may be paid at the Warrantholder's election either (i) by cash or check, or (ii) by surrender of all or a portion of the Warrant for shares of Common Stock to be exercised under this Agreement and, if applicable, an amended Agreement setting forth the remaining number of shares purchasable hereunder, as determined below ("Net Issuance"). If the Warrantholder elects the Net Issuance method, the Company will issue shares of Common Stock in accordance with the following formula:

$$X = \frac{Y(A-B)}{A}$$

Where: X = the number of shares of Common Stock to be issued to the Warrantholder.

Y = the number of shares of Common Stock requested to be exercised under this Agreement.

A = the then-current fair market value of one (1) share of Common Stock at the time of exercise of this Warrant.

B = the then-effective Exercise Price.

For purposes of the above calculation, the current fair market value of shares of Common Stock shall mean with respect to each share of Common Stock:

(i) at all times when the Common Stock is traded on a national securities exchange, inter-dealer quotation system or over-the-counter bulletin board service, the average of the closing prices over a ten (10) day consecutive period ending three days before the day the current fair market value of the securities is being determined;

(ii) if the exercise is in connection with a Merger Event, the fair market value of a share of Common Stock shall be deemed to be the per share value received by the holders of the outstanding shares of Common Stock pursuant to such Merger Event as determined in accordance with the definitive transaction documents executed among the parties in connection therewith; or

(iii) in cases other than as described in the foregoing clauses (i) and (ii), the current fair market value of a share of Common Stock shall be determined in good faith by the Company's Board of Directors.

Upon partial exercise by either cash or Net Issuance, prior to the expiration or earlier termination hereof, the Company shall promptly issue an amended Agreement representing the remaining number of shares purchasable hereunder. All other terms and conditions of such amended Agreement shall be identical to those contained herein, including, but not limited to the Effective Date hereof.

(b) Exercise Prior to Expiration. To the extent this Warrant is not previously exercised as to all shares of Common Stock subject hereto, and if the then-current fair market value of one share of Common Stock is greater than the Exercise Price then in effect, or, in the case of a Liquid Sale, where the value per share of Common Stock (as determined as of the closing of such Liquid Sale in accordance with the definitive agreements executed by the parties in connection with such Merger Event) to be paid to the holders thereof is greater than the Exercise Price then in effect, this Agreement shall be deemed automatically exercised on a Net Issuance basis pursuant to Section 3(a) (even if not surrendered) as of immediately before its expiration determined in accordance with Section 2. For purposes of such automatic exercise, the fair market value of one share of Common Stock upon such expiration shall be determined pursuant to Section 3(a). To the extent this Warrant or any portion hereof is deemed automatically exercised pursuant to this Section 3(b), the Company agrees to promptly notify the Warrantholder of the number of shares of Common Stock if any, the Warrantholder is to receive by reason of such automatic exercise, and to issue or cause its transfer agent to issue a certificate or a book-entry credit to the Warrantholder evidencing such shares.

SECTION 4.RESERVATION OF SHARES.

During the term of this Agreement, the Company will at all times have authorized and reserved a sufficient number of shares of its Common Stock to provide for the exercise of the rights to purchase Common Stock as provided for herein. If at any time during the term hereof the number of authorized but unissued shares of Common Stock shall not be sufficient to permit exercise of this Warrant in full, the Company will take such corporate action as may, in the opinion of its counsel, be necessary to increase its authorized but unissued shares of Common Stock to such number of shares as shall be sufficient for such purposes.

SECTION 5.NO FRACTIONAL SHARES OR SCRIP.

No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Agreement, but in lieu of such fractional shares the Company shall make a cash payment therefor in an amount equal to the product of (a) the Exercise Price then in effect multiplied by (b) the fraction of a share.

SECTION 6.NO RIGHTS AS SHAREHOLDER.

Without limitation of any provision hereof, the Warrantholder agrees that this Agreement does not entitle the Warrantholder to any voting rights or other rights as a shareholder of the Company prior to the exercise of any of the purchase rights set forth in this Agreement.

SECTION 7.WARRANTHOLDER REGISTRY.

The Company shall maintain a registry showing the name and address of the registered holder of this Agreement. The Warrantholder's initial address, for purposes of such registry, is set forth in Section 12(g) below. The Warrantholder may change such address by giving written notice of such changed address to the Company.

SECTION 8.ADJUSTMENT RIGHTS.

The Exercise Price and the number of shares of Common Stock purchasable hereunder are subject to adjustment from time to time, as follows:

(a) Merger Event. In connection with a Merger Event that is a Liquid Sale, this Warrant shall, on and after the closing thereof, automatically and without further action on the part of any party or other person, represent the right to receive the consideration payable on or in respect of all shares of Common Stock that are issuable hereunder as of immediately prior to the closing of such Merger Event less the Purchase Price for all such shares of Common Stock (such consideration to include both the

consideration payable at the closing of such Merger Event and all deferred consideration payable thereafter, if any, including, but not limited to, payments of amounts deposited at such closing into escrow and payments in the nature of earn-outs, milestone payments or other performance-based payments), and such Merger Event consideration shall be paid to the Warrantholder as and when it is paid to the holders of the outstanding shares of Common Stock. In connection with a Merger Event that is not a Liquid Sale, the Company shall cause the successor or surviving entity to assume this Warrant and the obligations of the Company hereunder on the closing thereof, and thereafter this Warrant shall be exercisable for the same number and type of securities or other property as the Warrantholder would have received in consideration for the shares of Common Stock issuable hereunder had it exercised this Warrant in full as of immediately prior to such closing, at an aggregate Exercise Price no greater than the aggregate Exercise Price in effect as of immediately prior to such closing, and subject to further adjustment from time to time in accordance with the provisions of this Warrant. The provisions of this Section 8(a) shall similarly apply to successive Merger Events.

(b) Reclassification of Shares. Except for Merger Events subject to Section 8(a), if the Company at any time shall, by combination, reclassification, exchange or subdivision of securities or otherwise, change any of the securities as to which purchase rights under this Agreement exist into the same or a different number of securities of any other class or classes of securities, this Agreement shall thereafter represent the right to acquire such number and kind of securities as would have been issuable as the result of such change with respect to the securities which were subject to the purchase rights under this Agreement immediately prior to such combination, reclassification, exchange, subdivision or other change. The provisions of this Section 8(b) shall similarly apply to successive combination, reclassification, exchange, subdivision or other change.

(c) Subdivision or Combination of Shares. If the Company at any time shall combine or subdivide its Common Stock, (i) in the case of a subdivision, the Exercise Price shall be proportionately decreased and the number of shares for which this Warrant is exercisable shall be proportionately increased, or (ii) in the case of a combination, the Exercise Price shall be proportionately increased and the number of shares for which this Warrant is exercisable shall be proportionately decreased.

(d) Dividends. If the Company at any time while this Agreement is outstanding and unexpired shall:

(i) pay a dividend with respect to the outstanding shares of Common Stock payable in additional shares of Common Stock, then the Exercise Price shall be adjusted, from and after the date of determination of shareholders entitled to receive such dividend, to that price determined by multiplying the Exercise Price in effect immediately prior to such date of determination by a fraction (A) the numerator of which shall be the total number of shares of Common Stock outstanding immediately prior to such dividend or distribution, and (B) the denominator of which shall be the total number of shares of Common Stock outstanding immediately after such dividend or distribution, and the number of shares of Common Stock for which this Warrant is exercisable shall be proportionately increased; or

(ii) make any other dividend or distribution on or with respect to Common Stock, except any dividend or distribution (A) in cash, or (B) specifically provided for in any other clause of this Section 8, then, in each such case, provision shall be made by the Company such that the Warrantholder shall receive upon exercise or conversion of this Warrant a proportionate share of any such dividend or distribution as though it were the holder of the Common Stock (or other stock for which the Common Stock is convertible) as of the record date fixed for the determination of the shareholders of the Company entitled to receive such dividend or distribution.

(e) Notice of Certain Events. If: (i) the Company shall declare any dividend or distribution upon its outstanding Common Stock, payable in stock, cash, property or other securities (provided that the Warrantholder in its capacity as lender under the Loan Agreement consents to such dividend); (ii) the Company shall offer for subscription pro rata to the holders of its Common Stock any additional shares of stock of any class or other rights; (iii) there shall be any Merger Event; or (iv) there shall be any voluntary dissolution, liquidation or winding up of the Company; then, in connection with each such event, the Company shall give the Warrantholder notice thereof at the same time and in the same manner as it gives notice thereof to the holders of outstanding Common Stock. In addition, if at any time the number of shares of Common Stock (or other securities of any other class or classes of securities of the Company for which this Warrant is then exercisable) outstanding is reduced such that the number of shares of Common Stock or other securities issuable upon exercise of this Warrant shall exceed five percent (5%) of the then outstanding class of such securities, then, within three (3) business days of such event, the Company shall give the Warrantholder written notice thereof.

SECTION 9.REPRESENTATIONS, WARRANTIES AND COVENANTS OF THE COMPANY.

(a) Reservation of Common Stock. The Company covenants and agrees that all shares of Common Stock that may be issued upon the exercise of the rights represented by this Warrant will, upon issuance, be validly issued and outstanding, fully paid and non-assessable, and will be free of any taxes, liens, charges or encumbrances of any nature whatsoever; provided, that the Common Stock issuable pursuant to this Agreement may be subject to restrictions on transfer under state and/or federal securities laws. The Company has made available to the Warrantholder true, correct and complete copies of its Charter and bylaws currently in effect. The issuance of certificates or book-entry credit for shares of Common Stock upon exercise of this Warrant shall be made without charge to the Warrantholder for any issuance tax in respect thereof, or other cost incurred by the Company in connection with such exercise and related issuance of shares of Common Stock. The Company further covenants and agrees that the Company will, at all times during the term hereof, have authorized and reserved, free from preemptive rights, a sufficient number of shares of Common Stock to provide for the exercise of the rights represented by this Warrant.

(b) Due Authority. The execution and delivery by the Company of this Agreement and the performance of all obligations of the Company hereunder, including the issuance to the Warrantholder of the right to acquire the shares of Common Stock, have been duly authorized by all necessary corporate action on the part of the Company. This Agreement: (i) does not violate the Charter or the Company's current bylaws; (ii) does not contravene any law or governmental rule, regulation or order applicable to the Company; and (iii) except as could not reasonably be expected to have a Material Adverse Effect (as defined in the Loan Agreement), does not and will not contravene any provision of, or constitute a default under, any indenture, mortgage, contract or other instrument to which the Company is a party or by which it is bound. This Agreement constitutes a legal, valid and binding agreement of the Company, enforceable in accordance with its terms, except as may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws relating to or affecting creditors' rights generally (including, without limitation, fraudulent conveyance laws) and by general principles of equity, regardless of whether considered in a proceeding in equity or at law.

(c) Consents and Approvals. No consent or approval of, giving of notice to, registration with, or taking of any other action in respect of any state, federal or other governmental authority or agency is required with respect to the execution, delivery and performance by the Company of its obligations under this Agreement, except for the filing of notices pursuant to Regulation D under the Act and any filing required by applicable state securities law, which filings will be effective by the time required thereby.

(d) Exempt Transaction. Subject to the accuracy of the Warrantholder's representations in Section 10, the issuance of the Common Stock upon exercise of this Agreement will constitute a transaction exempt

from (i) the registration requirements of Section 5 of the Act, in reliance upon Section 4(a)(2) thereof, and (ii) the qualification requirements of the applicable state securities laws.

(e) Information Rights. At all times (if any) prior to the earlier to occur of (i) the date on which all shares of Common Stock issued on exercise of this Warrant have been sold, or (ii) the expiration or earlier termination of this Warrant, when the Company shall not be required to file reports pursuant to Section 13 or 15(d) of the Exchange Act or shall not have timely filed all such required reports, the Warrantholder shall be entitled to the information rights contained in Section 7.1(b) of the Loan Agreement, provided that the confidentiality provisions contained in Section 11.13 of the Loan Agreement shall apply to any information received under this section, and in any such event Section 7.1(b) and Section 11.13 of the Loan Agreement is hereby incorporated into this Agreement by this reference as though fully set forth herein, provided, however, that the Company shall not be required to deliver a Compliance Certificate once all Indebtedness (as defined in the Loan Agreement) owed by the Company to the Warrantholder has been repaid.

(a) Rule 144 Compliance. The Company shall, at all times prior to the earlier to occur of (i) the date of sale or other disposition by the Warrantholder of this Warrant or all shares of Common Stock issued on exercise of this Warrant, or (ii) the expiration or earlier termination of this Warrant if the Warrant has not been exercised in full or in part on such date, use all commercially reasonable efforts to timely file all reports required under the Exchange Act and otherwise timely take all actions necessary to permit the Warrantholder to sell or otherwise dispose of this Warrant and the shares of Common Stock issued on exercise hereof pursuant to Rule 144 promulgated under the Act ("Rule 144"), provided that the foregoing shall not apply in the event of a Merger Event following which the successor or surviving entity is not subject to the reporting requirements of the Exchange Act. If the Warrantholder proposes to sell Common Stock issuable upon the exercise of this Agreement in compliance with Rule 144, then, upon the Warrantholder's written request to the Company, the Company shall furnish to the Warrantholder, within five (5) business days after receipt of such request, a written statement confirming the Company's compliance with the filing and other requirements of such Rule 144.

(b) Registration of Shares. Within six (6) months following the exercise of this Warrant, the Company shall prepare and file with the Securities and Exchange Commission a registration statement covering the resale of the shares issued pursuant to such Exercise Notice for an offering to be made on a continuous basis and shall use best efforts to cause such registration statement to be declared effective. Notwithstanding the foregoing, the Company shall not be required to comply with this Section 9(g) in the event that the shares issued pursuant to the exercise of this warrant may be sold under Rule 144 or another similar exemption under the Securities Act.

SECTION 10.REPRESENTATIONS AND COVENANTS OF THE WARRANTHOLDER.

This Agreement has been entered into by the Company in reliance upon the following representations and covenants of the Warrantholder:

(a) Investment Purpose. This Warrant and the shares issued on exercise hereof will be acquired for investment and not with a view to the sale or distribution of any part thereof in violation of applicable federal and state securities laws, and the Warrantholder has no present intention of selling or engaging in any public distribution of the same except pursuant to a registration or exemption.

(b) Private Issue. The Warrantholder understands that (i) the Common Stock issuable upon exercise of this Agreement is not, as of the Effective Date, registered under the Act or qualified under applicable state securities laws on the grounds that the issuance contemplated by this Agreement will be exempt from the registration and qualifications requirements thereof, and (ii) the Company's reliance on exemption from such registration is predicated on the representations set forth in this Section 10.

(c) Financial Risk. The Warrantholder has such knowledge and experience in financial and business matters as to be capable of evaluating the merits and risks of its investment, and has the ability to bear the economic risks of its investment.

(d) Accredited Investor. The Warrantholder is an "accredited investor" within the meaning of Rule 501 of Regulation D promulgated under the Act, as presently in effect ("Regulation D").

(e) No Short Sales. The Warrantholder has not at any time on or prior to the Effective Date engaged in any short sales or equivalent transactions in the Common Stock. Warrantholder agrees that at all times from and after the Effective Date and on or before the expiration or earlier termination of this Warrant, it shall not engage in any short sales or equivalent transactions in the Common Stock.

SECTION 11.TRANSFERS.

Subject to compliance with applicable federal and state securities laws, this Agreement and all rights hereunder are transferable, in whole or in part, without charge to the holder hereof (except for transfer taxes) upon surrender of this Agreement properly endorsed, provided, that as long as no Event of Default (as defined in the Loan Agreement) has occurred and is continuing, the holder hereof may not, without the Company's prior written consent, transfer this Agreement or any portion hereof, or any shares issued upon any exercise hereof, to any person or entity who directly competes with the Company (as reasonably determined by Agent upon consultation with Company), it being acknowledged that in all cases, any transfer to an affiliate of the holder hereof shall be allowed. Each taker and holder of this Agreement, by taking or holding the same, consents and agrees that this Agreement, when endorsed in blank, shall be deemed negotiable, and that the holder hereof, when this Agreement shall have been so endorsed and its transfer recorded on the Company's books, shall be treated by the Company and all other persons dealing with this Agreement as the absolute owner hereof for any purpose and as the person entitled to exercise the rights represented by this Agreement. Subject to the first sentence of this Section 11, the transfer of this Agreement shall be recorded on the books of the Company upon receipt by the Company of a notice of transfer in the form attached hereto as Exhibit III (the "Transfer Notice"), at its principal offices and the payment to the Company of all transfer taxes and other governmental charges imposed on such transfer. Until the Company receives such Transfer Notice, the Company may treat the registered owner hereof as the owner for all purposes. Notwithstanding anything herein or in any legend to the contrary, the Company shall not require an opinion of counsel in connection with any sale, assignment or other transfer by the Warrantholder of this Warrant (or any portion hereof or any interest herein) or of any shares of Common Stock issued upon any exercise hereof to an affiliate (as defined in Regulation D) of the Warrantholder, provided that such affiliate is an "accredited investor" as defined in Regulation D.

SECTION 12.MISCELLANEOUS.

(a) Effective Date. The provisions of this Agreement shall be construed and shall be given effect in all respects as if it had been executed and delivered by the Company on the date hereof. This Agreement shall be binding upon any successors or assigns of the Company.

(b) Remedies. In the event of any default hereunder, the non-defaulting party may proceed to protect and enforce its rights either by suit in equity and/or by action at law, including but not limited to an action for damages as a result of any such default, and/or an action for specific performance for any default where the Warrantholder will not have an adequate remedy at law and where damages will not be readily ascertainable.

(c) No Impairment of Rights. The Company will not, by amendment of its Charter or through any other means, avoid or seek to avoid the observance or performance of any of the terms of this Agreement, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be reasonably necessary or appropriate in order to protect the rights of the Warrantholder against impairment.

(d) Additional Documents. In the event the Company shall not be required to file reports pursuant to Section 13 or 15(d) of the Exchange Act, the Company agrees to supply such other documents as the Warrantholder may from time to time reasonably request to value this Warrant for Warrantholder's accounting or reporting requirements and/or to evaluate whether to exercise (in cash or a net issuance basis) this Warrant.

(e) Attorneys' Fees. In any litigation, arbitration or court proceeding between the Company and the Warrantholder relating hereto, the prevailing party shall be entitled to reasonable and documented attorneys' fees and expenses and all costs of proceedings incurred in enforcing this Agreement. For the purposes of this Section 12(e), attorneys' fees shall include without limitation fees incurred in connection with the following: (i) contempt proceedings; (ii) discovery; (iii) any motion, proceeding or other activity of any kind in connection with an insolvency proceeding; (iv) garnishment, levy, and debtor and third party examinations; and (v) post-judgment motions and proceedings of any kind, including without limitation any activity taken to collect or enforce any judgment.

(f) Severability. In the event any one or more of the provisions of this Agreement shall for any reason be held invalid, illegal or unenforceable, the remaining provisions of this Agreement shall be unimpaired, and the invalid, illegal or unenforceable provision shall be replaced by a mutually acceptable valid, legal and enforceable provision, which comes closest to the intention of the parties underlying the invalid, illegal or unenforceable provision.

(g) Notices. Except as otherwise provided herein, any notice, demand, request, consent, approval, declaration, service of process or other communication that is required, contemplated, or permitted under this Agreement or with respect to the subject matter hereof shall be in writing, and shall be deemed to have been validly served, given, delivered, and received upon the earlier of: (i) personal delivery to the party to be notified, (ii) when sent by confirmed telex or electronic transmission if sent during normal business hours of the recipient, if not, then on the next business day, (iii) five (5) days after having been sent by registered or certified mail, return receipt requested, postage prepaid, or (iv) one day after deposit with a nationally recognized overnight courier, specifying next day delivery, with written verification of receipt, and shall be addressed to the party to be notified as follows:

If to the Warrantholder:

HERCULES CAPITAL, INC.
Legal Department
Attention: Chief Legal Officer, Cristy Barnes, Himani Bhalla and Briana Gironda
400 Hamilton Avenue, Suite 310
Palo Alto, CA 94301
Facsimile: [Redacted]
Telephone: [Redacted]

With a copy to (which shall not constitute notice):

DLA PIPER LLP (US)
401 B Street, Suite 1700
San Diego, California 92101-4297
Attn: Matt Schwartz, Esq.
Facsimile: [Redacted]
Telephone: [Redacted]

If to the Company:

AKERO THERAPEUTICS, INC.
Attention: Jonathan M. Young; William White
601 Gateway Blvd, Suite 350

South San Francisco, CA 94080
email: [Redacted]

With a copy to (which shall not constitute notice):

GOODWIN PROCTER LLP
100 Northern Avenue

Boston, MA 02210
Attention: Mark D. Smith, Esq.

Facsimile: [Redacted]
Telephone: [Redacted]

or to such other address as each party may designate for itself by like notice.

(h) Entire Agreement; Amendments. This Agreement constitutes the entire agreement and understanding of the parties hereto in respect of the subject matter hereof, and supersedes and replaces in their entirety any prior proposals, term sheets, letters, negotiations or other documents or agreements, whether written or oral, with respect to the subject matter hereof. None of the terms of this Agreement may be amended except by an instrument executed by each of the parties hereto.

(i) Headings. The various headings in this Agreement are inserted for convenience only and shall not affect the meaning or interpretation of this Agreement or any provisions hereof.

(j) Advice of Counsel. Each of the parties represents to each other party hereto that it has discussed (or had an opportunity to discuss) with its counsel this Agreement and, specifically, the provisions of Sections 12(n), 12(o), 12(p), 12(q) and 12(r).

(k) No Strict Construction. The parties hereto have participated jointly in the negotiation and drafting of this Agreement. In the event an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as if drafted jointly by the parties hereto and no presumption or burden of proof shall arise favoring or disfavoring any party by virtue of the authorship of any provisions of this Agreement.

(l) No Waiver. No omission or delay by the Warrantholder at any time to enforce any right or remedy reserved to it, or to require performance of any of the terms, covenants or provisions hereof by the Company at any time designated, shall be a waiver of any such right or remedy to which the Warrantholder is entitled, nor shall it in any way affect the right of the Warrantholder to enforce such provisions thereafter during the term of this Agreement.

(m) Survival. All agreements, representations and warranties contained in this Agreement or in any document delivered pursuant hereto shall be for the benefit of the Warrantholder and shall survive the execution and delivery of this Agreement and the expiration or other termination of this Agreement.

(n) Governing Law. This Agreement has been negotiated and delivered to the Warrantholder in the State of California, and shall be deemed to have been accepted by the Warrantholder in the State of California. Delivery of Common Stock to the Warrantholder by the Company under this Agreement is due in the State of California. This Agreement shall be governed by, and construed and enforced in accordance with, the laws of the State of California, excluding conflict of laws principles that would cause the application of laws of any other jurisdiction.

(o) Consent to Jurisdiction and Venue. All judicial proceedings arising in or under or related to this Agreement may be brought in any state or federal court of competent jurisdiction located in the State of California. By execution and delivery of this Agreement, each party hereto generally and unconditionally: (i) consents to personal jurisdiction in Santa Clara County, State of California; (ii) waives any objection as to jurisdiction or venue in Santa Clara County, State of California; (iii) agrees not to assert any defense based on lack of jurisdiction or venue in the aforesaid courts; and (iv) irrevocably agrees to be bound by any judgment rendered thereby in connection with this Agreement. Service of process on any party hereto in any action arising out of or relating to this Agreement shall be effective if given in accordance with the requirements for notice set forth in Section 12(g), and shall be deemed effective and received as set forth in Section 12(g). Nothing herein shall affect the right to serve process in any other manner permitted by law or shall limit the right of either party to bring proceedings in the courts of any other jurisdiction.

(p) Mutual Waiver of Jury Trial. Because disputes arising in connection with complex financial transactions are most quickly and economically resolved by an experienced and expert person and the parties wish applicable state and federal laws to apply (rather than arbitration rules), the parties desire that their disputes arising under or in connection with this Warrant be resolved by a judge applying such applicable laws. EACH OF THE COMPANY AND THE WARRANTHOLDER SPECIFICALLY WAIVES ANY RIGHT IT MAY HAVE TO TRIAL BY JURY OF ANY CAUSE OF ACTION, CLAIM, CROSS-CLAIM, COUNTERCLAIM, THIRD PARTY CLAIM OR ANY OTHER CLAIM (COLLECTIVELY, "CLAIMS") ASSERTED BY THE COMPANY AGAINST THE WARRANTHOLDER OR ITS ASSIGNEE OR BY THE WARRANTHOLDER OR ITS ASSIGNEE AGAINST THE COMPANY RELATING TO THIS WARRANT. This waiver extends to all such Claims, including Claims that involve persons or entities other the Company and the Warrantholder; Claims that arise out of or are in any way connected to the relationship between the Company and the Warrantholder; and any Claims for damages, breach of contract, specific performance, or any equitable or legal relief of any kind, arising out of this Agreement.

(q) Arbitration. If the Mutual Waiver of Jury Trial set forth in Section 12(p) is ineffective or unenforceable, the parties agree that all Claims shall be submitted to binding arbitration in accordance with the commercial arbitration rules of JAMS (the "Rules"), such arbitration to occur before one arbitrator, which arbitrator shall be a retired California state judge or a retired Federal court judge. Such proceeding shall be conducted in Santa Clara County, State of California, with California rules of evidence and discovery applicable to such arbitration. The decision of the arbitrator shall be binding on the parties, and shall be final and nonappealable to the maximum extent permitted by law. Any judgment rendered by the arbitrator may be entered in a court of competent jurisdiction and enforced by the prevailing party as a final judgment of such court.

(r) Pre-arbitration Relief. In the event Claims are to be resolved by arbitration, either party may seek from a court of competent jurisdiction identified in Section 12(o), any prejudgment order, writ or other relief and have such prejudgment order, writ or other relief enforced to the fullest extent permitted by law notwithstanding that all Claims are otherwise subject to resolution by binding arbitration.

(s) Counterparts. This Agreement and any amendments, waivers, consents or supplements hereto may be executed in any number of counterparts (including by facsimile or electronic delivery (PDF), and by different parties hereto in separate counterparts, each of which when so delivered shall be deemed an original, but all of which counterparts shall constitute but one and the same instrument.

(t) Specific Performance. The parties hereto hereby declare that it is impossible to measure in money the damages which will accrue to the Warrantholder by reason of the Company's failure to perform any of the obligations under this Agreement and agree that the terms of this Agreement shall be specifically enforceable by the Warrantholder. If the Warrantholder institutes any action or proceeding to specifically enforce the provisions hereof, any person against whom such action or proceeding is brought hereby waives

the claim or defense therein that the Warrantholder has an adequate remedy at law, and such person shall not offer in any such action or proceeding the claim or defense that such remedy at law exists.

(u) Lost, Stolen, Mutilated or Destroyed Warrant. If this Warrant is lost, stolen, mutilated or destroyed, the Company may, on such terms as to indemnity or otherwise as it may reasonably impose (which shall, in the case of a mutilated Warrant, include the surrender thereof), issue a new Warrant of like denomination and tenor as this Warrant so lost, stolen, mutilated or destroyed. Any such new Warrant shall constitute an original contractual obligation of the Company, whether or not the allegedly lost, stolen, mutilated or destroyed Warrant shall be at any time enforceable by anyone.

(v) Legends. To the extent required by applicable laws, this Warrant and the shares of Common Stock issuable hereunder (and the securities issuable, directly or indirectly, upon conversion of such shares of Common Stock, if any) may be imprinted with a restricted securities legend in substantially the following form:

THIS SECURITY HAS NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "ACT"), OR ANY APPLICABLE STATE SECURITIES LAWS, AND MAY NOT BE SOLD, OFFERED FOR SALE, PLEDGED OR HYPOTHECATED IN THE ABSENCE OF AN EFFECTIVE REGISTRATION RELATED THERETO OR, SUBJECT TO SECTION 11 OF THE WARRANT AGREEMENT DATED JUNE 15, 2022, BETWEEN THE COMPANY AND HERCULES CAPITAL, INC., AN OPINION OF COUNSEL (WHICH MAY BE COMPANY COUNSEL) REASONABLY SATISFACTORY TO THE COMPANY THAT SUCH REGISTRATION IS NOT REQUIRED UNDER THE ACTOR ANY STATE SECURITIES LAWS.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the parties hereto have caused this Warrant Agreement to be executed by its officers thereunto duly authorized as of the Effective Date.

COMPANY:

AKERO THERAPEUTICS, INC.

By: /s/ Andrew Cheng
Name: Andrew Cheng
Title: President and Chief Executive Officer

WARRANTHOLDER:

HERCULES CAPITAL, INC.

By: /s/ Seth Meyer
Name: Seth Meyer
Title: Chief Financial Officer

EXHIBIT I

NOTICE OF EXERCISE

To: AKERO THERAPEUTICS, INC.

(1) The undersigned Warrantholder hereby elects to purchase [_____] shares of the Common Stock of AKERO THERAPEUTICS, INC., pursuant to the terms of the Warrant Agreement dated the 15th day of June, 2022 (the "Warrant Agreement") between AKERO THERAPEUTICS, INC. and the Warrantholder, and [CASH PAYMENT: tenders herewith payment of the Purchase Price in full, together with all applicable transfer taxes, if any.] [NET ISSUANCE: elects pursuant to Section 3(a) of the Warrant Agreement to effect a Net Issuance.]

(2) Please issue a certificate or certificates or book-entry credit(s) representing said shares of Common Stock in the name of the undersigned or in such other name as is specified below.

_____
(Name)

_____
(Address)

WARRANTHOLDER: HERCULES CAPITAL, INC.

By: _____
Name: _____
Title: _____

EXHIBIT II

1. ACKNOWLEDGMENT OF EXERCISE

The undersigned, AKERO THERAPEUTICS, INC., hereby acknowledges receipt of the "Notice of Exercise" from HERCULES CAPITAL, INC. to purchase [____] shares of the Common Stock of AKERO THERAPEUTICS, INC. pursuant to the terms of the Warrant Agreement by and between AKERO THERAPEUTICS, INC. and HERCULES CAPITAL, INC. dated the 15th day of June, 2022 (the "Warrant Agreement"), and further acknowledges that [_____] shares remain subject to purchase under the terms of the Warrant Agreement.

COMPANY: AKERO THERAPEUTICS, INC.

By: _____

Title: _____

Date: _____

EXHIBIT III

TRANSFER NOTICE

(To transfer or assign the foregoing Agreement execute this form and supply required information. Do not use this form to purchase shares.)

FOR VALUE RECEIVED, the foregoing Agreement and all rights evidenced thereby are hereby transferred and assigned to

_____
(Please Print)

whose address is_____

_____

Dated: _____

Holder's Signature: _____

Holder's Address: _____

_____

Signature Guaranteed: _____

NOTE: The signature to this Transfer Notice must correspond with the name as it appears on the face of the Agreement, without alteration or enlargement or any change whatever. Officers of corporations and those acting in a fiduciary or other representative capacity should file proper evidence of authority to assign the foregoing Agreement.

EXHIBIT 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO EXCHANGE ACT RULES 13a-14(a) AND 15d-14(a),
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Andrew Cheng, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Akero Therapeutics, 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.

Date: August 5, 2022

/s/ ANDREW CHENG
Andrew Cheng, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION OF CHIEF 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

I, William White, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Akero Therapeutics, 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.

Date: August 5, 2022

/s/ WILLIAM WHITE
William White
Executive Vice President, Chief Financial Officer and Head of Corporate Development
(Principal Financial and Accounting Officer)

EXHIBIT 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Andrew Cheng, certify pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report on Form 10-Q of Akero Therapeutics, Inc. for the quarterly period ended June 30, 2022, fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act and that the information contained in such Quarterly Report on Form 10-Q fairly presents, in all material respects, the financial condition and result of operations of Akero Therapeutics, Inc.

Dated: August 5, 2022

/s/ ANDREW CHENG
Andrew Cheng, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

I, William White, certify pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report on Form 10-Q of Akero Therapeutics, Inc. for the quarterly period ended June 30, 2022, fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act and that the information contained in such Quarterly Report on Form 10-Q fairly presents, in all material respects, the financial condition and result of operations of Akero Therapeutics, Inc.

Dated: August 5, 2022

/s/ WILLIAM WHITE
William White
Executive Vice President, Chief Financial Officer and Head of Corporate Development
(Principal Financial and Accounting Officer)