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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2024

or

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

For the transition period from_to

Commission File Number: 001-38978

FULCRUM THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**47-4839948**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
26 Landsdowne Street	
Cambridge	
,	
Massachusetts	**02139**
(Address of principal executive offices)	**(Zip Code)**

(617) 651-8851
(Registrant's telephone number, including area code)

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

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

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

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

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

Large accelerated filer	☐	Accelerated filer	☐
	☒		
Non-accelerated filer			☒
		Smaller reporting company	

☒

Emerging growth company

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

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

As of July 24, 2024, the registrant had

62,400,770
shares of common stock, $0.001 par value per share, outstanding.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements, which reflect our current views with respect to, among other things, our operations and financial performance. 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, objectives of management and expected market growth are forward-looking statements. The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “might,” “outlook,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “would,” and the negative version of these words and other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words and include, among other statements, express or implied statements regarding:

- our ongoing clinical trials of losmapimod and pociredir, including the effects of the revised inclusion and exclusion criteria on our trial of pociredir;
- the timing of and our ability to submit applications for, and obtain and maintain regulatory approvals for losmapimod, pociredir and any other product candidates;
- our expectations regarding our ability to fund our operating expenses and capital expenditure requirements with our cash, cash equivalents, and marketable securities;
- the initiation, timing, progress and results of our current and future preclinical studies and clinical trials and our research and development programs;
- our plans to develop and, if approved, subsequently commercialize losmapimod, pociredir and any other product candidates, including in combination with other drugs and therapies;
- the potential advantages of our product candidates;
- the rate and degree of market acceptance and clinical utility of our products, if our product candidates are approved;
- our estimates regarding the potential market opportunity for our product candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;
- the impact of our organizational streamlining and realignment of resources, including our anticipated cash runway;
- the initiation, timing, progress and results of our drug target discovery screening programs;
- our intellectual property position;
- the progress and results of our recent collaboration and license agreement with Genzyme Corporation, a wholly-owned subsidiary of Sanofi, or Sanofi, under our collaboration agreement with MyoKardia, Inc., or MyoKardia, a wholly-owned subsidiary of Bristol-Myers Squibb Company, or under our exclusive global license agreement with CAMP4 Therapeutics Corp., or CAMP4;
- our ability to identify additional products, product candidates or technologies with significant commercial potential that are consistent with our commercial objectives;
- our estimates regarding expenses, future revenue, timing of any future revenue, capital requirements and needs for additional financing;
- the impact of government laws and regulations;
- our competitive position;
- developments relating to our competitors and our industry;
- our ability to maintain and establish collaborations, license agreements or obtain additional funding;
- the impact global pandemics or other geopolitical events on our business and operations, including our clinical trials and development plans, as well as our future financial results; and
- our expectations regarding the time during which we will be an emerging growth company or a smaller reporting company as defined under the federal securities laws.

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. Such forward looking statements are subject to various risks and uncertainties. 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" and "Management's Discussion and Analysis of Results of Operations" sections, that we believe 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, license agreements, joint ventures or investments we may make or enter into.

You should read this Quarterly Report on Form 10-Q and the documents that we have filed as exhibits to this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results may be materially different from what we expect. The forward-looking statements contained in this Quarterly Report on Form 10-Q are made as of the date of this Quarterly Report on Form 10-Q, and 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 applicable law.

SUMMARY RISK FACTORS

Our business is subject to a number of risks that if realized could materially affect our business, financial condition, results of operations, cash flows and access to liquidity. These risks are discussed more fully in the "Risk Factors" section of this Quarterly Report on Form 10-Q. Our principal risks include the following:

- We have incurred significant losses since our inception. Our net loss was $97.3 million for the year ended December 31, 2023. Our net income was $28.5 million for the six months ended June 30, 2024, primarily due to the $80.0 million upfront payment under our collaboration and license agreement with Sanofi. Excluding the potential for future milestone payments under our collaboration and license agreement with Sanofi, we expect to incur losses over the next several years and may never achieve or maintain profitability. As of June 30, 2024, we had an accumulated deficit of $481.1 million.

- We will need substantial additional funding. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts. We expect to devote substantial financial resources to our ongoing and planned activities, particularly as we continue our clinical trials of losmapimod and pociredir and continue research and development and initiate additional clinical trials of, and seek regulatory approval for, these and other product candidates.

- We are early in our development efforts, and we only have two product candidates in clinical trials. If we are unable to commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed.

- Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. The results of preclinical studies and early clinical trials may not be predictive of future results. We may incur additional costs or experience further delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

- Because we are developing some of our product candidates for the treatment of diseases in which there is limited clinical experience and, in some cases, using new endpoints or methodologies, the U.S. Food and Drug Administration, or FDA, or other regulatory authorities may not consider the endpoints of our clinical trials to predict or provide clinically meaningful results.

- If serious adverse events or unacceptable side effects are identified during the development of our product candidates, including others' product candidates in the same class of drugs, we may need to abandon or limit our development of some of our product candidates.

- We may not be successful in our efforts to use our discovery approach to build a pipeline of product candidates.

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

- We rely, and expect to continue to rely, on contract manufacturing organizations, or CMOs, to manufacture our product candidates. If we are unable to enter into such arrangements as expected or if such organizations do not meet our supply requirements, development and/or commercialization of our product candidates may be delayed.

• We rely, and expect to continue to rely, on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, which may harm our business.

• We have entered into, and may in the future enter into, collaborations and license agreements with third parties for the discovery, development or commercialization of product candidates, including our recent collaboration and license agreement with Sanofi, our collaboration with MyoKardia, and our license agreement with CAMP4. If our collaborations are not successful or we are not able to develop product candidates that we license-in, we may not be able to capitalize on the market potential of these product candidates and our business could be adversely affected.

• If we are unable to obtain, maintain, enforce and protect patent protection for our technology and product candidates or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully develop and commercialize our technology and product candidates may be adversely affected.

• If we fail to comply with our obligations in our intellectual property licenses and funding arrangements with third parties, or otherwise experience disruptions to our business relationships with our licensors, we could lose intellectual property rights that are important to our business.

• Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults or non-performance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations and financial condition and results of operations.

• Our business was negatively impacted by the COVID-19 pandemic and may in the future be impacted by any future pandemics, as well as other geopolitical events that can impact our clinical trials or the supply chain, such as the Russian invasion of Ukraine or recent hostilities in Israel and the Gaza Strip. These events may continue to, and any future pandemics may, adversely impact economies worldwide, which could result in adverse effects on our business and operations.

Table of Contents

In this Quarterly Report on Form 10-Q, unless otherwise stated or as the context otherwise requires, references to "Fulcrum," "Fulcrum Therapeutics," "the Company," "we," "us," "our" and similar references refer to Fulcrum Therapeutics, Inc. together with its consolidated subsidiary. The Fulcrum Therapeutics logo and other trademarks or service marks of Fulcrum Therapeutics, Inc. appearing in this Quarterly Report on Form 10-Q are the property of Fulcrum Therapeutics, Inc. This Quarterly Report on Form 10-Q also contains registered marks, trademarks and trade names of other companies. All other trademarks, registered marks and trade names appearing herein are the property of their respective holders.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

Fulcrum Therapeutics, Inc.

Consolidated Balance Sheets

(In thousands, except share and per share amounts)

(Unaudited)

	June 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 86,702	$ 25,563
Marketable securities	187,076	210,658
Unbilled accounts receivable	2,333	537
Prepaid expenses and other current assets	4,175	5,441
Total current assets	280,286	242,199
Property and equipment, net	4,408	5,216
Operating lease right-of-use assets	6,357	7,176
Restricted cash	1,216	1,092
Other assets	1,989	2,011
Total assets	$ 294,256	$ 257,694
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,584	$ 2,757
Accrued expenses and other current liabilities	7,033	8,726
Operating lease liability, current	2,082	2,192
Total current liabilities	12,699	13,675
Operating lease liability, excluding current portion	7,570	8,629

Other liabilities, excluding current portion	197	197
Total liabilities	20,466	22,501
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, $ 0.001 par value; 5,000,000 shares authorized; no shares issued or outstanding	—	—
Common stock, $ 0.001 par value; 200,000,000 shares authorized; 62,250,631 and 61,915,367 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	62	62
Additional paid-in capital	755,228	744,940
Accumulated other comprehensive loss	(366)	(136)
Accumulated deficit	(481,134)	(509,673)
Total stockholders' equity	273,790	235,193
Total liabilities and stockholders' equity	$ 294,256	$ 257,694

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

Fulcrum Therapeutics, Inc.

Consolidated Statements of Operations and Comprehensive Income (Loss)

(In thousands, except per share data)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Collaboration revenue	$ 80,000	$ 880	$ 80,000	$ 1,175
Operating expenses:				
Research and development	17,261	17,849	37,034	34,564
General and administrative	10,247	10,323	20,308	21,843
Total operating expenses	27,508	28,172	57,342	56,407
Income (loss) from operations	52,492	(27,292)	22,658	(55,232)
Other income, net	2,917	3,509	5,881	6,670
Net income (loss)	$ 55,409	$ (23,783)	$ 28,539	$ (48,562)
Net income (loss) per share, basic	$ 0.89	$ (0.38)	$ 0.46	$ (0.80)
Net income (loss) per share, diluted	$ 0.87	$ (0.38)	$ 0.45	$ (0.80)
Weighted-average common shares outstanding, basic	62,205	61,794	62,095	60,764
Weighted-average common shares outstanding, diluted	63,587	61,794	63,684	60,764
Comprehensive income (loss):				
Net income (loss)	$ 55,409	$ (23,783)	$ 28,539	$ (48,562)
Other comprehensive gain (loss):				
Unrealized gain (loss) on marketable securities	68	(549)	(230)	(403)
Total other comprehensive gain (loss)	68	(549)	(230)	(403)
Comprehensive income (loss)	$ 55,477	$ (24,332)	$ 28,309	$ (48,965)

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

Fulcrum Therapeutics, Inc.

Consolidated Statements of Stockholders' Equity

(In thousands, except share amounts)

(Unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2022	52,099,211	52	612,025	(797)	(412,338)	198,942
Issuance of common stock in connection with public offering, net of issuance costs	9,615,384	10	117,336	—	—	117,346
Issuance of common stock under employee benefit plans	38,903	—	348	—	—	348
Vesting of restricted stock awards	5,496	—	—	—	—	—
Stock-based compensation expense	—	—	4,253	—	—	4,253
Unrealized gain on marketable securities	—	—	—	146	—	146
Net loss	—	—	—	—	(24,779)	(24,779)
Balance at March 31, 2023	61,758,994	62	733,962	(651)	(437,117)	296,256
Issuance of common stock under employee benefit plans	50,912	—	141	—	—	141
Vesting of restricted stock awards	12,648	—	—	—	—	—
Stock-based compensation expense	—	—	3,363	—	—	3,363
Unrealized loss on marketable securities	—	—	—	(549)	—	(549)
Net loss	—	—	—	—	(23,783)	(23,783)
Balance at June 30, 2023	61,822,554	62	737,466	(1,200)	(460,900)	275,428
Balance at December 31, 2023	61,915,367	62	744,940	(136)	(509,673)	235,193

Issuance of common stock under employee benefit plans	214,094	—	1,651	—	—	1,651
Vesting of restricted stock awards	11,550	—	—	—	—	—
Stock-based compensation expense	—	—	3,916	—	—	3,916
Unrealized loss on marketable securities	—	—	—	(298)	—	(298)
Net loss	—	—	—	—	(26,870)	(26,870)
Balance at March 31, 2024	62,141,011	$ 62	$ 750,507	$ (434)	$ (536,543)	$ 213,592
Issuance of common stock under employee benefit plans	98,844	—	377	—	—	377
Vesting of restricted stock awards	10,776	—	—	—	—	—
Stock-based compensation expense	—	—	4,344	—	—	4,344
Unrealized gain on marketable securities	—	—	—	68	—	68
Net income	—	—	—	—	55,409	55,409
Balance at June 30, 2024	62,250,631	$ 62	$ 755,228	$ (366)	$ (481,134)	$ 273,790

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

Fulcrum Therapeutics, Inc.

Consolidated Statements of Cash Flows

(In thousands)

(Unaudited)

	Six Months Ended June 30,	
	2024	**2023**
Operating activities		
Net income (loss)	$ 28,539	$ (48,562)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation expense	855	1,133
Stock-based compensation expense	8,260	7,616
Net accretion of discounts on marketable securities	(2,295)	(3,078)
Changes in operating assets and liabilities:		
Unbilled accounts receivable	(1,796)	(427)
Prepaid expenses and other current assets	1,266	242
Operating lease assets and liabilities	(350)	(337)
Other assets	22	110
Accounts payable	807	251
Accrued expenses and other liabilities	(1,693)	(1,428)
Deferred revenue	—	(421)
Net cash provided by (used in) operating activities	$ 33,615	$ (44,901)
Investing activities		
Purchases of marketable securities	(119,054)	(143,832)
Maturities of marketable securities	144,702	70,132
Purchases of property and equipment	(28)	(366)
Net cash provided by (used in) investing activities	25,620	(74,066)
Financing activities		

Proceeds from issuance of common stock in connection with public offerings, net of issuance costs	—	117,345
Proceeds from issuance of common stock under benefit plans, net	2,028	490
Net cash provided by financing activities	2,028	117,835
Net increase (decrease) in cash, cash equivalents and restricted cash	61,263	(1,132)
Cash, cash equivalents, and restricted cash, beginning of period	26,655	36,190
Cash, cash equivalents, and restricted cash, end of period	$ 87,918	$ 35,058
Supplemental cash flow information		
Cash paid for operating lease liabilities	$ 1,478	$ 1,646
Non-cash investing and financing activities:		
Property and equipment purchases unpaid at end of period	$ 19	$ 47

The following table provides a reconciliation of the cash, cash equivalents, and restricted cash balances as of each of the periods shown above:

	June 30, 2024	June 30, 2023
Cash and cash equivalents	$ 86,702	$ 33,966
Restricted cash	1,216	1,092
Total cash, cash equivalents, and restricted cash	$ 87,918	$ 35,058

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

1. Nature of the Business and Basis of Presentation

Fulcrum Therapeutics, Inc. (the "Company" or "Fulcrum") was incorporated in Delaware on August 18, 2015. The Company is focused on developing small molecules to improve the lives of patients with genetically-defined rare diseases in areas of high unmet medical need.

The Company is subject to a number of risks similar to other companies in the biotechnology industry, including, but not limited to, risks of failure of preclinical studies and clinical trials, dependence on key personnel, protection of proprietary technology, reliance on third party organizations, risks of obtaining regulatory approval for any product candidate that it may develop, development by competitors of technological innovations, compliance with government regulations, and the need to obtain additional financing. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing, and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel infrastructure and extensive compliance-reporting capabilities. Even if the Company's 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 conformity with generally accepted accounting principles in the United States of America ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

The accompanying consolidated financial statements and footnotes to the financial statements have been prepared on the same basis as the most recently audited annual consolidated financial statements and, in the opinion of management, reflect all normal recurring adjustments necessary for the fair presentation of the Company's financial position as of June 30, 2024 and the results of its operations and its cash flows for the three and six months ended June 30, 2024 and 2023. The results for the three and six months ended June 30, 2024 are not necessarily indicative of results to be expected for the year ending December 31, 2024, any other interim periods, or any future year or period. These consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and the notes thereto for the year ended December 31, 2023 included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on February 27, 2024 (the "Annual Report on Form 10-K").

Sales of Common Stock

In January 2023, the Company completed a public offering of its common stock and issued and sold

9,615,384
shares of common stock at a public offering price of $

13.00
per share, resulting in net proceeds of $

117.3
million after deducting underwriting discounts and commissions and offering expenses.

Liquidity

The Company has incurred recurring losses and negative cash flows from operations since inception and has primarily funded its operations with proceeds from the sale of shares of its capital stock and from upfront payments received from collaboration and license agreements. As of June 30, 2024, the Company had an accumulated deficit of $

481.1

million. The Company expects its operating losses and negative operating cash flows to continue into the foreseeable future as it continues to expand its research and development efforts. The Company expects to finance its future cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements.

The Company expects that its cash, cash equivalents, and marketable securities will be sufficient to fund its operating expenses and capital expenditure requirements for at least 12 months from the date of issuance of these financial statements. However, the Company has based this estimate on assumptions that may prove to be wrong, and its operating plan may change as a result of many factors currently unknown to it. As a result, the Company could deplete its capital resources sooner than it currently expects. If the Company is unable to raise additional funds through equity or debt financings when needed, it may be required to delay, limit, reduce or terminate development or future commercialization efforts or grant rights to develop and market product candidates that it would otherwise prefer to develop and market itself.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiary, Fulcrum Therapeutics Securities Corp., which is a Massachusetts subsidiary created to buy, sell, and hold securities. All intercompany transactions and balances have been eliminated.

Summary of Significant Accounting Policies

The significant accounting policies and estimates used in the preparation of the accompanying consolidated financial statements are described in the Company’s audited consolidated financial statements for the year ended December 31, 2023 included in the Company’s Annual Report on Form 10-K. There have been no material changes in the Company’s significant accounting policies during the six months ended June 30, 2024, except as noted below with respect to the Company's accounting policies related to collaborative arrangements.

Collaborative Arrangements

At contract inception, the Company analyzes its collaboration arrangements to assess whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and are exposed to significant risks and rewards dependent on the commercial success of such activities, and therefore within the scope of ASC Topic 808, *Collaborative Arrangements* (ASC 808). This assessment is performed on an ongoing basis throughout the collaboration based on changes in the responsibilities of the parties in the arrangement. For collaboration arrangements within the scope of ASC 808 that contain multiple elements, the Company first determines which elements of the collaboration are deemed to be within the scope of ASC 808 and which elements of the collaboration are more reflective of a vendor-customer relationship and are therefore within the scope of ASC 606, *Revenue from Contracts with Customers* (ASC 606).

For elements of collaboration arrangements that are accounted for pursuant to ASC 808, an appropriate recognition method is determined and applied consistently, either by analogy to authoritative accounting literature or by applying a reasonable and rational policy election. The Company evaluates the income statement classification for presentation of amounts due from or owed to collaborators associated with multiple activities in a collaboration arrangement based on the nature of each separate activity. The Company made an accounting policy election to account for research and development reimbursements received from its collaboration partner that are outside of the scope of ASC 606 as a reduction of research and development expenses to best reflect the economics and nature of the transaction in the context of the unit-of-account.

See Note 2, “Summary of Significant Accounting Policies”, in the Company’s audited consolidated financial statements for the year ended December 31, 2023 included in the Company’s Annual Report on Form 10-K for the Company's accounting policies for arrangements within the scope of ASC 606.

Use of Estimates

The preparation of financial statements in accordance with GAAP requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the financial statements, and the reported amount of expenses during the reported periods. Estimates inherent in the preparation of these consolidated financial statements include, but are not limited to, estimates related to revenue recognition, accrued expenses, stock-based compensation expense, and income taxes. The Company bases its estimates on historical experience and other market specific or other relevant assumptions it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates as there are changes in circumstances, facts and experience. Actual results could differ from those estimates or assumptions.

Off-Balance Sheet Risk and Concentrations of Credit Risk

The Company has no significant off-balance sheet risk such as foreign exchange contracts, option contracts, or other foreign hedging arrangements. Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash, cash equivalents, marketable securities, and restricted cash. The Company's cash, cash equivalents, and restricted cash are deposited in accounts at large financial institutions. The Company believes it is not exposed to significant credit risk due to the financial strength of the depository institutions in which the cash, cash equivalents and restricted cash are held. The Company maintains its cash equivalents in money market funds that invest in U.S. Treasury securities, U.S. Treasury securities, and commercial paper. The Company's marketable securities consist of U.S. Treasury securities, corporate bonds, and commercial paper, and potentially subject the Company to concentrations of credit risk. The Company has adopted an investment policy that limits the amounts the Company may invest in any one type of investment. The Company has not experienced any credit losses and does not believe it is exposed to any significant credit risk on these funds.

Recent Accounting Pronouncements

During the periods presented, the Company was not required to adopt any recently issued accounting standards. The Company does not expect any recently issued accounting standards to have a material impact on its financial statements.

3. Fair Value Measurements

The following tables present information about the Company's financial assets measured at fair value on a recurring basis and indicate the fair value hierarchy classification of such fair values as of June 30, 2024 and December 31, 2023 (in thousands):

	Fair Value Measurements at June 30, 2024			
	Total	Level 1	Level 2	Level 3
Cash equivalents:				
Money market funds	$ 32,041	$ 32,041	$ —	$ —
U.S. Treasury securities	54,661	—	54,661	—
Marketable securities:				
U.S. Treasury securities	25,235	—	25,235	—
Government agency securities	14,903	—	14,903	—
Commercial paper	4,454	—	4,454	—
Corporate bonds	142,484	—	142,484	—
Total	$ 273,778	$ 32,041	$ 241,737	$ —

	Fair Value Measurements at December 31, 2023			
	Total	Level 1	Level 2	Level 3
Cash equivalents:				

Money market funds	25,563	25,563		
	$	$	$ —	$ —
Marketable securities:				
U.S. Treasury securities	14,215	—	14,215	—
Government agency securities	65,107	—	65,107	—
Commercial paper	17,889	—	17,889	—
Corporate bonds	113,447	—	113,447	—
Total	236,221	25,563	210,658	—
	$	$	$	$

There were

no

transfers between fair value levels during the three and six months ended June 30, 2024.

4. Cash Equivalents and Marketable Securities

Cash equivalents and marketable securities consisted of the following as of June 30, 2024 and December 31, 2023 (in thousands):

	Fair Value Measurements at June 30, 2024			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash equivalents:				
Money market funds	$ 32,041	$ —	$ —	$ 32,041
U.S. Treasury securities	54,663	—	(2)	54,661
Total cash equivalents	86,704	—	(2)	86,702
Marketable securities:				
U.S. Treasury securities	25,242	—	(7)	25,235
Government agency securities	14,925	—	(22)	14,903
Commercial paper	4,459	—	(5)	4,454
Corporate bonds	142,814	2	(332)	142,484
Total marketable securities	187,440	2	(366)	187,076
Total cash equivalents and marketable securities	$ 274,144	$ 2	$ (368)	$ 273,778

	Fair Value Measurements at December 31, 2023			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash equivalents:				
Money market funds	$ 25,563	$ —	$ —	$ 25,563
Total cash equivalents	25,563	—	—	25,563

Marketable securities:

U.S. Treasury securities	14,229	10	(24)	14,215
Government agency securities	65,182	23	(98)	65,107
Commercial paper	17,891	8	(10)	17,889
Corporate bonds	113,492	90	(135)	113,447
Total marketable securities	210,794	131	(267)	210,658
Total cash equivalents and marketable securities	$ 236,357	$ 131	$ (267)	$ 236,221

There were no sales of marketable securities during the three and six months ended June 30, 2024. As of June 30, 2024, the Company held 57 debt securities that were in an unrealized loss position for less than 12 months with an aggregate fair value of $ 159.0 million. As of June 30, 2024, the Company held 7 debt securities that were in an unrealized loss position for greater than 12 months with an aggregate fair value of $ 18.9 million. As of June 30, 2024, the aggregate fair value of marketable securities with a remaining contractual maturity of greater than one year was $ 3.1 million.

The Company has the intent and ability to hold its debt securities until recovery. As a result, the Company did not record any charges for credit-related impairments for its marketable securities for the three and six months ended June 30, 2024.

5. Property and Equipment, Net

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

	June 30, 2024	December 31, 2023
Lab equipment	$ 9,613	$ 9,682
Furniture and fixtures	600	600
Computer equipment	393	393
Software	199	199
Leasehold improvements	7,121	7,102
Total property and equipment	17,926	17,976
Less: accumulated depreciation	(13,518)	(12,760)
Property and equipment, net	$ 4,408	$ 5,216

Depreciation expense for the three months ended June 30, 2024 and 2023 was $

0.4
million and $

0.6
million, respectively. Depreciation expense for the six months ended June 30, 2024 and 2023 was $

0.9
million and $

1.1
million, respectively.

6. Additional Balance Sheet Detail

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

	June 30, 2024	December 31, 2023
Prepaid expenses	$ 2,957	$ 3,658
Prepaid sign-on bonuses subject to vesting provisions	17	71
Interest income receivable	1,201	1,712

Total prepaid expenses and other current assets	$ 4,175	$ 5,441

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

	June 30, 2024	December 31, 2023
External research and development	$ 3,235	$ 3,164
Payroll and benefits	2,723	4,712
Professional services	769	454
Other	306	396
Total accrued expenses and other current liabilities	$ 7,033	$ 8,726

7. Preferred Stock

As of June 30, 2024 and December 31, 2023,

5,000,000

shares of undesignated preferred stock were authorized.

No

shares of preferred stock were issued or outstanding as of June 30, 2024 and December 31, 2023.

No
dividends have been declared since inception.

8. Common Stock

As of June 30, 2024 and December 31, 2023,

200,000,000

shares of common stock, $

0.001

par value per share, were authorized.

Each share of common stock entitles the holder to

one
vote on all matters submitted to a vote of the Company's stockholders . Common stockholders are not entitled to receive dividends, unless declared by the Company's board of directors, subject to the preferential dividend rights of any preferred stock then outstanding.

No
dividends have been declared or paid by the Company since its inception.

As of June 30, 2024 and December 31, 2023, the Company has reserved for future issuance the following number of shares of common stock:

	June 30, 2024	December 31, 2023
Shares reserved for exercises of outstanding stock options	12,547,394	9,972,217
Shares reserved for vesting of restricted stock units	115,995	75,017
Shares reserved for future issuance under the 2019 Stock Incentive Plan	2,709,603	3,157,537
Shares reserved for future issuance under the 2019 Employee Stock Purchase Plan	1,701,485	1,346,125
Shares reserved for future issuance under the 2022 Inducement Stock Incentive Plan	1,407,603	837,877
	18,482,080	15,388,773

9. Stock-based Compensation Expense

2016 Stock Incentive Plan

In July 2016, the Company adopted the 2016 Stock Incentive Plan (the "2016 Plan"), which provided for the grant of restricted stock awards, restricted stock units, incentive stock options, non-statutory stock options, and other stock-based awards to the Company's eligible employees, officers, directors, consultants, and advisors. As of the effective date of the 2019 Stock Incentive Plan (the "2019 Plan"), and as of June 30, 2024,

no

shares remained available for future issuance under the 2016 Plan. Any options or other awards outstanding under the 2016 Plan remain outstanding and effective.

2019 Stock Incentive Plan

On July 2, 2019, the Company's stockholders approved the 2019 Plan, which became effective on July 17, 2019. The 2019 Plan provides for the grant of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock units and other stock-based awards to the Company's officers, employees, directors, consultants and advisors. The number of shares initially reserved for issuance under the 2019 Plan was

2,017,142

shares, plus the shares of common stock remaining available for issuance under the 2016 Plan as of July 17, 2019. The number of shares reserved was annually increased on January 1, 2020 and will be increased each January 1 thereafter through January 1, 2029 by the least of (i)

2,000,000

shares, (ii)

4

% of the number of shares of the Company's common stock outstanding on the first day of each such year or (iii) an amount determined by the Company's board of directors. On January 1, 2024, the number of shares reserved for issuance under the 2019 Plan was increased by

2,000,000

shares. As of June 30, 2024, there were

2,709,603

shares available for future issuance under the 2019 Plan.

The shares of common stock underlying any awards that expire, terminate, or are otherwise surrendered, cancelled, forfeited or repurchased by the Company under the 2016 Plan or the 2019 Plan will be added back to the shares of common stock available for issuance under the 2019 Plan. As of July 17, 2019, no further awards will be made under the 2016 Plan.

2022 Inducement Stock Incentive Plan

In February 2022, the Company's board of directors adopted the 2022 Inducement Stock Incentive Plan (the "Inducement Plan"), pursuant to which the Company may grant, subject to the terms of the Inducement Plan and Nasdaq rules, nonstatutory stock options, stock appreciation rights, restricted

stock awards, restricted stock units, and other stock-based awards. The Company initially reserved a total of

1,750,000

shares of common stock for the issuance of awards under the Inducement Plan. The number of shares reserved and available for issuance under the Inducement Plan can be increased at any time with the approval of the Company's board of directors. The Inducement Plan permits the board of directors, a delegated committee of the board of directors, or a delegated officer of the Company to grant the stock-based awards available under the Inducement Plan to attract key employees for the growth of the Company. Effective March 8, 2023, the Company's board of directors amended the Inducement Plan to increase the number of shares reserved for issuance by

2,000,000

shares. Effective May 18, 2023, the Company's board of directors amended the Inducement Plan to increase the number of shares reserved for issuance by

1,400,000

shares. Effective June 17, 2024, the Company's board of directors amended the Inducement Plan to increase the number of shares reserved for issuance by

1,000,000

shares. As of June 30, 2024, there were

1,407,603

shares available for future issuance under the Inducement Plan.

Stock Options

Stock options granted by the Company typically vest over a four-year period and have a ten year contractual term. Shares issued upon the exercise of stock options are issued from the Company's pool of authorized but unissued common stock. In addition to stock options granted under the 2019 Plan and 2016 Plan, the Company has granted stock options as material inducements to employment in accordance with Nasdaq Listing Rule 5635(c)(4), which were granted outside of the 2019 Plan and 2016 Plan. The following table summarizes the Company's stock option activity during the six months ended June 30, 2024:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2023	9,972,217	$ 8.44	8.49	$ 15,114,074
Granted	2,964,458	7.55		
Exercised	(239,727)	7.37		
Cancelled	(149,554)	8.89		
Outstanding at June 30, 2024	12,547,394	$ 8.24	8.43	$ 12,343,417
Exercisable at June 30, 2024	4,705,847	$ 10.54	7.47	$ 3,434,971

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 as of the balance sheet date for those options that had exercise prices lower than the fair value of the Company's common stock.

The weighted average grant date fair value of stock options granted in the three and six months ended June 30, 2024 was $

5.79
per share and $

6.17
per share, respectively. The weighted average grant date fair value of stock options granted in the three and six months ended June 30, 2023 was $

2.50
per share and $

4.83
per share, respectively. The total intrinsic value of stock options exercised during the three and six months ended June 30, 2024 was $

0.1
million and $

0.9
million, respectively. The total intrinsic value of stock options exercised during the three and six months ended June 30, 2023 was

zero
and $

0.2
million, respectively.

The fair value of stock options granted during the three and six months ended June 30, 2024 and 2023 has been calculated on the date of grant using the following weighted average assumptions:

	Three Months Ended June 30, 2024	Three Months Ended June 30, 2023	Six Months Ended June 30, 2024	Six Months Ended June 30, 2023
Risk-free interest rate	4.3%	3.5%	4.1%	3.6%
Expected dividend yield	0.0%	0.0%	0.0%	0.0%
Expected term (years)	5.8	6.1	6.0	6.1
Expected stock price volatility	102.8%	100.2%	103.1%	98.2%

Restricted Stock Units

The Company has also granted restricted stock units. The shares of common stock underlying restricted stock units typically vest over a four-year period. The shares of common stock are recorded in stockholders' equity as they vest.

The following table summarizes the Company's restricted stock unit activity during the six months ended June 30, 2024:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2023	75,017	$ 10.77
Granted	70,445	6.95
Vested	(22,326)	10.65
Cancelled	(7,141)	9.32
Unvested at June 30, 2024	115,995	$ 8.56

Stock-based Compensation Expense

The total compensation cost recognized in the statements of operations and comprehensive loss associated with all stock-based compensation awards granted by the Company is as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
General and administrative	$ 2,681	$ 2,391	$ 5,268	$ 5,799
Research and development	1,663	972	2,992	1,817
Total stock-based compensation expense	$ 4,344	$ 3,363	$ 8,260	$ 7,616

As of June 30, 2024, the Company had an aggregate of $

40.2

million of unrecognized stock-based compensation expense, which is expected to be recognized over a weighted average period of 2.80 years.

2019 Employee Stock Purchase Plan

On July 2, 2019, the Company's stockholders approved the 2019 Employee Stock Purchase Plan (the "ESPP"), which became effective on July 17, 2019. A total of

252,142

shares of common stock were initially reserved for issuance under the ESPP. In addition, the number of shares of common stock reserved under the ESPP was increased on January 1, 2020, and will be increased annually on each January 1 thereafter through January 1, 2029, by the least of (i)

428,571

shares of common stock, (ii)

1

% of the number of shares of the Company's common stock outstanding on the first day of each such year or (iii) an amount determined by the Company's board of directors. On January 1, 2024, the number of shares reserved for issuance under the 2019 ESPP was increased by

428,571

shares. As of June 30, 2024, there were

1,701,485

shares available for future issuance under the ESPP.

10. License and Collaboration Agreements

Sanofi Agreement

In May 2024, the Company entered into a collaboration and license agreement (the "Sanofi Agreement") with Genzyme Corporation ("Sanofi") pursuant to which the Company granted Sanofi an exclusive license under certain intellectual property rights to commercialize losmapimod, an oral small molecule for the treatment of facioscapulohumeral muscular dystrophy ("FSHD"), outside of the United States.

Pursuant to a mutually agreed global development plan, the Company will continue to conduct the ongoing Phase 3 clinical trial for losmapimod for the treatment of FSHD. The Company and Sanofi will equally share global development costs. In addition to activities conducted under a mutually agreed global development plan, Sanofi will also have the right to conduct certain development activities that are solely intended to support obtaining or maintaining regulatory approval outside of the United States. The Company will have the sole right to manufacture for its activities under the global development plan and for commercialization in the United States and, subject to the terms of a supply agreement, the Company will supply Sanofi's clinical and commercial supply requirements of losmapimod until Sanofi elects to take over such manufacturing responsibilities.

Per the terms of the Sanofi Agreement, Sanofi made an upfront license payment of $

80.0

million to the Company during the second quarter of 2024. The Company is also eligible to receive up to an additional $

975.0

million in specified regulatory and sales-based milestones, and Sanofi will pay the Company tiered royalties ranging from low-teens to mid-twenties percent of Sanofi's and any of its affiliates' and sublicensees' annual net sales of losmapimod outside the United States. The royalties are payable on a product-by-product basis during a specified royalty term, and may be reduced in specified circumstances.

During the term of the Sanofi Agreement, the Company may not research, develop, manufacture, commercialize, use, or otherwise exploit any compound or product that binds or otherwise modulates p38a/b MAPK anywhere in the world, other than losmapimod in the United States.

The Sanofi Agreement continues on a country-by-country and product-by-product basis until the last to expire royalty term for a product in a country, at which time the Sanofi Agreement expires with respect to such product in such country. Either party has the right to terminate the Sanofi Agreement if the other party has materially breached its obligations under the Sanofi Agreement and such breach has not been cured within the applicable cure period. Sanofi also has the right to terminate the Sanofi Agreement for convenience in its entirety or on a product-by-product or region-by-region (or country-by-country with respect to certain major

markets) basis. The Company also has the right to terminate the Sanofi Agreement if Sanofi terminates all bona fide material development and commercialization activities for a specified period and such cessation is not the result of certain agreed upon reasons.

The Company determined that the Sanofi Agreement contained three material promises: (i) the license granted to Sanofi to develop and commercialize losmapimod outside of the United States (the "losmapimod license"); (ii) the parties' joint global development activities for losmapimod; and (iii) the Sanofi territory-specific manufacturing activities for losmapimod, subject to the terms of a supply agreement. The Company considered the guidance in ASC 606 to determine which, if any, of the components of the losmapimod agreement are performance obligations with a customer and concluded that the losmapimod license and the Sanofi territory-specific manufacturing activities are within the scope of ASC 606 because Sanofi is the Company's customer in those transactions.

The Company evaluated the losmapimod license under ASC 606 and concluded that the losmapimod license is a functional intellectual property license and is a distinct performance obligation. The Company determined that Sanofi benefited from the losmapimod license at the time of grant, and therefore the related performance obligation is satisfied at a point in time.

The Company evaluated the Sanofi territory-specific manufacturing activities under ASC 606 and identified one material promise associated with manufacturing activities related to development and commercial supply of losmapimod. Given that Sanofi is not obligated to purchase any minimum amount or quantities of the development and commercial supply from the Company, the Company concluded that, for the purpose of ASC 606, the provision of manufacturing activities related to development and commercial supply of losmapimod in the Sanofi territory was an option but not a performance obligation of the Company at the inception of the Sanofi agreement and will be accounted for if and when exercised. The Company also concluded that there is no separate material right in connection with the development and commercial supply of losmapimod, as the expected pricing was not issued at a significant and incremental discount. Therefore, the manufacturing activities were excluded as a performance obligation at the outset of the arrangement. Additionally, the Company is entitled to sales milestones and royalties from Sanofi upon future sales of losmapimod in the Sanofi territory, and revenue will be recognized when the related sales occur. Costs that are incurred associated with the Sanofi territory-specific manufacturing activities are reimbursable from Sanofi and will be recognized as revenue.

For the purposes of ASC 606, the transaction price of the Sanofi Agreement as of the outset of the arrangement consists of the upfront cash payment of $80.0 million, which was allocated to the performance obligation related to the losmapimod license. The other potential milestone payments that the Company is eligible to receive under the Sanofi agreement have been excluded from the transaction price, as all the remaining milestone amounts were fully constrained based on the probability of achievement. The Company will re-evaluate the transaction price at the end of each reporting period and as uncertain events are resolved or other changes in circumstances occur, and if necessary, the Company will adjust its estimate of the transaction price, and any addition to the transaction price would be recognized as revenue when it becomes probable that inclusion would not lead to a significant revenue reversal. During the three months ended June 30, 2024, the Company recognized $

80.0
million of revenue associated with the upfront license payment.

For the parties' participation in global development for losmapimod, the Company concluded that those activities and cost-sharing payments related to such activities are within the scope of ASC 808, as both parties are active participants in the development activities and are exposed to significant risks and rewards of those activities under the Sanofi agreement. The Company assessed its relationship with Sanofi, the economics and nature of the global development activities, and the contractual terms of the Sanofi Agreement and concluded that, in accordance with its policy, payments to or reimbursements from Sanofi related to the global development activities will be accounted for as an increase to or reduction of research and development expenses. During the three months ended June 30, 2024, the Company recorded a $

2.3
million reduction in research and development expenses in connection with global development activities for losmapimod.

GSK Agreement

In February 2019, the Company entered into the right of reference and license agreement, as amended (the "GSK Agreement"), with subsidiaries of GlaxoSmithKline plc (collectively referred to as "GSK"), pursuant to which the Company has been granted an exclusive worldwide license to develop and commercialize losmapimod. Under the GSK Agreement, the Company also acquired reference rights to relevant regulatory and manufacturing documents and GSK's existing supply of losmapimod drug substance and product. The Company also has the right to sublicense its rights under the license agreement, subject to certain conditions. The Company is obligated to use commercially reasonable efforts to develop and commercialize losmapimod at its sole cost. The Company is also responsible for costs related to the filing and maintenance of the licensed patent rights.

Under the GSK Agreement, the Company issued

12,500,000
shares of Series B Preferred Stock to GSK (all of which converted to common stock in connection with the Company's 2019 initial public offering). In addition, the Company may owe GSK up to $

37.5
million in certain specified clinical and regulatory milestones, including a $

5.0
million milestone that was achieved during 2022 and a $

2.5
million milestone that was achieved 2019, and up to $

60.0
million in certain specified sales milestones. The Company agreed to

pay tiered royalties on annual net sales of losmapimod that range from mid single-digit percentages to a low double-digit, but less than teens, percentage. The royalties are payable on a product-by-product and country-by-country basis, and may be reduced in specified circumstances.

The GSK Agreement may be terminated by either party for a material breach by the other, subject to notice and cure provisions. Unless earlier terminated, the GSK Agreement will continue in effect until the expiration of the Company's royalty obligations, which expire on a country-by-country basis on the later of (i) ten years after the first commercial sale in the country or (ii) approval of a generic version of losmapimod by the applicable regulatory agency.

The Company recognizes clinical and regulatory milestone payments when the underlying contingency is resolved and the consideration is paid or becomes payable. The milestone payments are capitalized or expensed depending on the nature of the associated asset as of the date of recognition.

MyoKardia Agreement

On July 20, 2020, the Company entered into the MyoKardia Collaboration Agreement, as amended, pursuant to which the Company granted to MyoKardia an exclusive worldwide license under certain intellectual property rights to research, develop, make, have made, use, have used, sell, have sold, offer for sale, have offered for sale, import, have imported, export, have exported, distribute, have distributed, market, have marketed, promote, have promoted, or otherwise exploit products directed against certain biological targets identified by the Company that are capable of modulating up to a certain number of genes of interest with relevance to certain genetically defined cardiomyopathies.

Pursuant to a mutually agreed research plan, the Company will perform assay screening and related research activities to identify and validate up to a specified number of potential cardiomyopathy gene targets ("Identified Targets") for further research, development, manufacture and commercialization by MyoKardia. The Company and MyoKardia will work together to determine how best to advance at each stage of the research activities under the research plan and to identify which of the Identified Targets, if any, meet the criteria set forth in the research plan (the "Cardiomyopathy Target Candidates"). Upon completion of the research plan, the parties will work together to prepare a final data package and MyoKardia may designate certain Cardiomyopathy Target Candidates for MyoKardia's further exploitation under the MyoKardia Collaboration Agreement (the "Cardiomyopathy Targets"). If MyoKardia does not designate any Cardiomyopathy Targets during the designated period, then the MyoKardia Collaboration Agreement will automatically terminate. If MyoKardia designates one or more Cardiomyopathy Targets, then MyoKardia will be obligated to use commercially reasonable efforts to seek regulatory approval for and to commercialize one product directed against an Identified Target in certain specified countries.

During the period in which the Company is performing the research activities pursuant to the research plan (the "Research Term") and for a specified period beyond the Research Term if MyoKardia designates a Cardiomyopathy Target, the Company may only use the data generated from such research activities for MyoKardia in accordance with the MyoKardia Collaboration Agreement. During the Research Term and for a specified period thereafter, the Company may not research, develop, manufacture, commercialize, use, or otherwise exploit any compound or product (a) that is a Compound or Product under the MyoKardia Collaboration Agreement that is directed against the Cardiomyopathy Target Candidates for the treatment, prophylaxis, or diagnosis of any indication or (b) for the treatment of any genetically defined cardiomyopathies shown to be related to certain specified genes of interest that are modulated by the Cardiomyopathy Targets.

Under the MyoKardia Collaboration Agreement, MyoKardia made a $

10.0
million upfront payment and a $

2.5
million payment as prepaid research funding to the Company in July 2020. MyoKardia agreed to reimburse the Company for the costs of the research activities not covered by the prepaid research funding, up to a maximum amount of total research funding (including the prepaid research funding). Upon the achievement of specified preclinical, development and sales milestones, the Company will be entitled to preclinical milestone payments, development milestone payments and sales milestone payments of up to $

298.5
million in the aggregate per target for certain Identified Targets, and of up to $

150.0
million in the aggregate per target for certain other Identified Targets. To date, the Company has achieved a $

2.5
million specified preclinical milestone. MyoKardia will also pay the Company tiered royalties ranging from a mid single-digit percentage to a low double-digit percentage based on MyoKardia's, and any of its affiliates' and sublicensees', annual worldwide net sales of products under the MyoKardia Collaboration Agreement directed against any Identified Target. The royalties are payable on a product-by-product basis during a specified royalty term, and may be reduced in specified circumstances.

The MyoKardia Collaboration Agreement continues on a country-by-country and product-by-product basis until the last to expire royalty term for a product, at which time the MyoKardia Collaboration Agreement expires with respect to such product in such country. Either party has the right to terminate the MyoKardia Collaboration Agreement if the other party has materially breached in the performance of its obligations under the MyoKardia Collaboration Agreement and such breach has not been cured within the

applicable cure period. MyoKardia also has the right to terminate the MyoKardia Collaboration Agreement for convenience in its entirety or on a target-by-target, product-by-product or molecule-by-molecule basis.

In July 2024, the Company entered into an amendment to the MyoKardia Collaboration Agreement, pursuant to which the Company and MyoKardia agreed to extend the Research Term.

Accounting Analysis

Identification of the Contract

The Company assessed the MyoKardia Collaboration Agreement and concluded that it represents a contract with a customer within the scope of ASC 606.

Identification of the Promises and Performance Obligations

The Company determined that the MyoKardia Collaboration Agreement contains the following promises: (i) an exclusive worldwide license under certain intellectual property rights, including rights to a specified number of potential cardiomyopathy gene targets identified by the Company for further research, development, manufacture and commercialization for the treatment, prophylaxis, or diagnosis of certain genetically defined cardiomyopathies that was conveyed at the inception of the arrangement (the "MyoKardia License"), (ii) research services to identify and validate potential biological targets (the "MyoKardia Research Services"), and (iii) participation in the joint steering committee (the "MyoKardia JSC").

The Company assessed the above promises and concluded that the MyoKardia License is not capable of being distinct from the MyoKardia Research Services given that the MyoKardia License has limited value without the performance of the MyoKardia Research Services and the MyoKardia Research Services can only be performed by the Company due to their specialized nature. Therefore, the Company has concluded that the MyoKardia License and the MyoKardia Research Services represent a single combined performance obligation.

The Company also assessed the participation on the MyoKardia JSC and concluded that the promise is quantitatively and qualitatively immaterial in the context of the MyoKardia Collaboration Agreement. Accordingly, the Company has disregarded its participation on the MyoKardia JSC as a performance obligation.

Determination of the Transaction Price

The Company received a non-refundable upfront payment of $

10.0
million, which the Company included in the transaction price. In December 2021, the Company achieved a $

2.5
million specified preclinical milestone associated with the MyoKardia Collaboration Agreement, which was previously constrained due to the significant uncertainty regarding whether such preclinical milestone would be achieved. The Company included this amount in the transaction price as of December 31, 2021. Based on the continued uncertainty associated with the achievement of any of the remaining preclinical and development milestone payments that the Company is eligible to receive, the Company has constrained the variable consideration associated with those milestone payments and excluded them from the transaction price. As part of its evaluation of constraining the preclinical and development milestones, the Company considered numerous factors, including the fact that the achievement of the preclinical and development milestones are contingent upon the results of the underlying preclinical and development activities and are thus outside of the control of the Company.

The Company also included in the transaction price the expected amount of costs to be reimbursed for the MyoKardia Research Services, which includes the $

2.5
million prepaid research funding payment that the Company received in the third quarter of 2020.

The Company reassesses the transaction price at the end of each reporting period and as uncertain events are resolved or other changes in circumstances occur, and, if necessary, adjusts its estimate of the transaction price. There was no change in the amount of variable consideration constrained during the three and six months ended June 30, 2024.

Any consideration related to sales milestone payments (including royalties) will be recognized when the related sales occur as these amounts have been determined to relate predominantly to the license granted to MyoKardia and therefore are recognized at the later of when the related sales occur or the performance obligation is satisfied.

Allocation of the Transaction Price to Performance Obligations

As noted above, the Company has identified a single performance obligation associated with the MyoKardia Collaboration Agreement. Therefore, the Company will allocate the entire amount of the transaction price to the identified single performance obligation.

Recognition of Revenue

The Company recognizes revenue related to the MyoKardia Collaboration Agreement over time as the MyoKardia Research Services are rendered. The Company has concluded that an input method is a representative depiction of the transfer of services under the MyoKardia Collaboration Agreement. The method of measuring progress towards the delivery of the services incorporates actual cumulative internal and external costs incurred relative to total internal and external costs expected to be incurred to satisfy the performance obligation. The period over which total costs are estimated reflects the Company's estimate of the period over which it will perform the MyoKardia Research Services. Changes in estimates of total internal and external costs expected to be incurred are recognized in the period of change as a cumulative catch-up adjustment. The Company satisfied its obligation to perform research services as of December 31, 2023.

During the three and six months ended June 30, 2024, the Company recognized

no

collaboration revenue associated with the MyoKardia Collaboration Agreement. During the three and six months ended June 30, 2023, the Company recognized $

0.9
million and $

1.2
million, respectively, of collaboration revenue associated with the MyoKardia Collaboration Agreement, which includes $

0.2
million and $

0.4
million, respectively, of revenue recognized that was in deferred revenue as of December 31, 2022. As of June 30, 2024 and December 31, 2023, the Company recorded

no

deferred revenue or accounts receivable associated with the MyoKardia Collaboration Agreement. As of June 30, 2024, the Company had received $

7.7
million of cost reimbursement payments under the MyoKardia Collaboration Agreement and $

2.5
million associated with the achievement of a preclinical milestone. As of December 31, 2023, the Company had received $

7.2
million of cost reimbursement payments under the MyoKardia Collaboration Agreement and $

2.5
million associated with the achievement of a preclinical milestone. As of June 30, 2024, the Company recorded

no
unbilled accounts receivable related to reimbursable research and development costs under the MyoKardia Collaboration Agreement for activities performed during the three months ended June 30, 2024. As of December 31, 2023, the Company recorded unbilled accounts receivable of $

0.5
million related to reimbursable research and development costs under the MyoKardia Collaboration Agreement for activities performed during the three months ended December 31, 2023.

CAMP4 Agreement

In July 2023, the Company entered into a license agreement (the "CAMP4 Agreement") with CAMP4 Therapeutics Corporation ("CAMP4") pursuant to which the Company received a worldwide exclusive license (including the right to sublicense) from CAMP4 to rights under its Diamond Blackfan Anemia ("DBA") program, which includes certain small molecule compounds, composition of matter and method of use patent rights, and know-how for the Company to research, develop, manufacture, use, commercialize or otherwise exploit therapeutic products in any indication, including the grant of a sublicense under certain intellectual property rights that CAMP4 has licensed under an agreement with Children's Medical Center Corporation ("CMCC").

The Company made an undisclosed upfront non-refundable, non-creditable payment to CAMP4. If the Company succeeds in developing and commercializing licensed products, CAMP4 will be eligible to receive (i) up to $

35.0
million in development and regulatory milestone payments, and (ii) up to $

35.0
million in sales milestone payments. CAMP4 is also eligible to receive royalties on worldwide net sales of licensed products ranging from mid-single digit to low-double digit, subject to potential reduction following loss of patent coverage, the launch of certain generic products or royalty stacking for licenses of third party intellectual property. The royalties will expire on a product-by-product and country-by-country basis upon the latest to occur of (i) the expiration of all valid patent claims covering the compounds in such country, (ii) the expiration of all regulatory exclusivities in such country, and (iii) 10 years following the first commercial sale in such country. The Company is responsible for the costs associated with the development and regulatory

approvals of licensed products.

Unless earlier terminated in accordance with its terms, the license agreement continues on a country-by-country and licensed product-by-licensed product basis until the expiration of the royalty term in each country, at which time the license agreement expires with respect to such licensed product in such country and the Company will have a fully-paid up, royalty-free and perpetual license to the licensed patent rights and know-how with respect to such licensed product in such country. CAMP4 has the right to terminate the license agreement in the event of the Company's non-payment (subject to cure periods and tolling for bona fide disputes). CAMP4 may also terminate the license agreement if the Company challenges certain patents sublicensed to the Company by CAMP4. Either party may terminate the license agreement in its entirety for the other party's material breach if such other party fails to cure the

breach. Either party may also terminate the agreement in its entirety upon certain insolvency events involving the other party. The Company has the right to terminate the license agreement with CAMP4 for any or no reason upon prior written notice to CAMP4.

The Company recognizes development and regulatory milestone payments when the underlying contingency is resolved and the consideration is paid or becomes payable. The milestone payments are capitalized or expensed depending on the nature of the associated asset as of the date of recognition.

11. Leases

Operating Leases

26 Landsdowne Street

In November 2017, the Company entered into a lease agreement for its current corporate headquarters comprising approximately

28,731

square feet of office and laboratory space at 26 Landsdowne Street in Cambridge, Massachusetts, commencing December 2017. The Company began to occupy and use the leased space for its intended purpose in June 2018. The lease ends on June 30, 2028. The Company has the option to extend the term of the lease for an additional five-year period, at the market rate, by giving the landlord written notice of its election to exercise the extension at least nine months prior to the original expiration of the lease term. The lease has a total commitment of $

25.1

million over the ten year term, and includes escalating rent payments. The lease provides the Company with an allowance for normal leasehold improvements of $

5.0

million. The lease agreement requires the Company to either pay a security deposit or maintain a letter of credit of $

1.1

million. The Company maintains a letter of credit for this lease and has recorded the cash held to secure the letter of credit as restricted cash on the consolidated balance sheet as of June 30, 2024 and December 31, 2023. Operating lease expense associated with this lease for the three and six months ended June 30, 2024 was approximately $

0.5

million and $

1.0

million, respectively. Variable lease expense associated with this lease for the three and six months ended June 30, 2024 was approximately $

0.2

million and $

0.4

million, respectively.

The future minimum lease payments associated with the 26 Landsdowne Street lease as of June 30, 2024, are as follows (in thousands):

2024(1)	1,304
2025	2,649
2026	2,729
2027	2,811
Thereafter	1,426
Total minimum lease payments	10,919
Less: imputed interest	(1,267)
Total lease liability	$ 9,652

1. Amounts are for the six months ending December 31, 2024.

125 Sidney Street

In November 2021, the Company entered into a lease agreement comprising approximately

12,196

square feet of office space at 125 Sidney Street in Cambridge, Massachusetts, commencing November 2021. The Company began recognizing rent expense associated with this lease during November 2021. The lease ended on March 31, 2024. The Company had the option to extend the term of the lease for two successive one-year periods, at the market rate, by giving the landlord written notice of its election to exercise the extension at least nine months prior to the original expiration of the lease term. The lease had a total commitment of $

1.7

million over the initial term, and included escalating rent payments. Operating lease expense associated with this lease for the three and six months ended June 30, 2024 was approximately

zero

and $

0.2

million, respectively.

No

variable lease expense was recorded associated with this lease for the three and six months ended June 30, 2024.

There are

no

future minimum lease payments associated with this lease as of June 30, 2024.

12. Commitments and Contingencies

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 arising out of the relationship between such parties and the Company. In addition, the Company has entered into indemnification agreements with members of its board of directors and senior

management 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 aware of any claims under indemnification arrangements, and it has

no

t accrued any liabilities related to such obligations as of June 30, 2024 or December 31, 2023.

Legal Proceedings

On April 28, 2023, a class action complaint was filed in the United States District Court for the District of New Jersey against the Company and current and former officers (the "Securities Action"). On May 19, 2023, the Securities Action was transferred to the United States District Court for the District of Massachusetts, captioned *Celano v. Fulcrum Therapeutics, Inc., et al*., Case No. 1:23-cv-11125-IT. On July 31, 2023, the court appointed a lead plaintiff, who filed an amended complaint on September 29, 2023. The Securities Action alleges violations of Section 10(b) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder against all defendants and control person violations of Section 20(a) against the individuals, related to the Company's February 2023 announcement that the U.S. Food and Drug Administration issued a clinical hold regarding the investigational new drug application for pociredir for the potential treatment of sickle cell disease. The Securities Action alleges that the defendants made misleading statements and omitted to disclose material information related to the clinical hold and seeks, among other things, compensatory damages in connection with an allegedly inflated stock price between March 3, 2022, and March 8, 2023, as well as attorneys' fees and costs. On November 28, 2023, all defendants filed a motion to dismiss the Securities Action. Briefing was completed on the motion in February 2024, and the motion is currently pending. The Company intends to defend vigorously against this litigation.

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 the costs related to its legal proceedings as they are incurred. Other than attorneys' fees and costs related to the defense of the Securities Action,

no
such costs have been incurred during the three and six months ended June 30, 2024.

13. Defined Contribution Plan

The Company has a defined contribution savings plan under Section 401(k) of the Internal Revenue Code (the " 401(k) Plan"). The 401(k) Plan covers all employees who meet defined minimum age and service requirements, and allows participants the option to elect to defer a portion of their annual compensation on a pretax basis. As currently established, the Company is not required to make contributions to the 401(k) Plan. The Company made $

0.2

million and $

0.4

million, respectively, in contributions to the 401(k) Plan for the three and six months ended June 30, 2024 and 2023.

14. Net Income (Loss) per Share

Basic net income per share is calculated by dividing net income (loss) by the weighted average number of shares of common stock outstanding during the period. Diluted net income per share is calculated by adjusting weighted average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period. For purposes of the diluted net income per share calculation, the effect of stock options and unvested restricted stock units on the weighted average number of shares is calculated using the treasury stock method. In periods with reported net operating losses, all common stock equivalents are deemed anti-dilutive such that basic net loss per share and diluted net loss per share are equal.

The calculation of net income (loss) and the number of shares used to compute basic and diluted net income (loss) per share for the three and six months ended June 30, 2024 and 2023 are as follows (in thousands, except per share data):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Net income (loss), basic and diluted	$ 55,409	$ (23,783)	$ 28,539	$ (48,562)
Weighted-average common shares outstanding, basic	62,205	61,794	62,095	60,764
Effect of diluted securities:				
Stock options	1,359	—	1,562	—
Restricted stock units	23	—	27	—

Weighted-average common shares outstanding, diluted	63,587	61,794	63,684	60,764
Net income (loss) per share, basic	$ 0.89	$ (0.38)	$ 0.46	$ (0.80)
Net income (loss) per share, diluted	$ 0.87	$ (0.38)	$ 0.45	$ (0.80)

The following common stock equivalents were excluded from the calculation of diluted net income (loss) per share for the periods indicated because including them would have had an anti-dilutive effect (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Stock options	8,028	10,115	7,306	10,115
Restricted stock units	27	85	18	85
Total	8,055	10,200	7,324	10,200

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

The following discussion and analysis of our financial condition and results of operations should be read together with our consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on February 27, 2024. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Quarterly Report on Form 10-Q, our actual results could differ materially from the results described in, or implied by, the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical-stage biopharmaceutical company focused on developing small molecules to improve the lives of patients with genetically defined rare diseases in areas of high unmet medical need. Our most advanced clinical-stage product candidate, losmapimod, is being developed for the potential treatment of facioscapulohumeral muscular dystrophy, or FSHD. Our other clinical product candidate is pociredir, which is being developed for the potential treatment of sickle cell disease, or SCD. We initiated REACH, a randomized, double-blind, placebo-controlled, multi-national Phase 3 clinical trial of losmapimod in the second quarter of 2022 and completed enrollment during September 2023, enrolling 260 patients. We expect to report topline data from REACH by the end of October 2024.

In January 2023, we announced interim data from our Phase 1b clinical trial of pociredir in SCD. We completed enrollment in the 6 mg and 2 mg dose cohorts, and do not plan to enroll additional subjects in these cohorts. Although we commenced enrollment in the 12 mg dose cohort, in February 2023 the FDA placed a full clinical hold on the investigational new drug, or IND, application for pociredir for SCD, which was lifted in August 2023. Following the clinical hold, we amended the protocol to revise the inclusion and exclusion criteria for the Phase 1b clinical trial to target subjects with higher disease severity. We reinitiated the Phase 1b clinical trial at the 12 mg once daily dose level in the fourth quarter of 2023, with that cohort expected to enroll approximately 10 subjects, to be followed by an additional cohort of approximately 10 subjects at the 20 mg once daily dose level. We expect to provide clinical data from this trial in 2025.

In May 2024, we entered into a collaboration and license agreement with Genzyme Corporation, a wholly-owned subsidiary of Sanofi, or Sanofi, pursuant to which we granted Sanofi an exclusive license under certain intellectual property rights to commercialize losmapimod outside of the United States. Pursuant to a mutually agreed global development plan, we will continue to conduct the ongoing REACH trial. We and Sanofi will equally share global development costs. In addition to potential future activities conducted under a mutually agreed global development plan, Sanofi will also have the right to conduct certain development activities that are solely intended to support obtaining or maintaining regulatory approval outside of the United States. We will have the sole right to manufacture for our activities under the global development plan and for commercialization in the United States and, subject to the terms of a supply agreement, we will supply Sanofi's clinical and commercial supply requirements of losmapimod until Sanofi elects to take over such manufacturing responsibilities.

Per the terms of the agreement, Sanofi made an upfront license payment of $80.0 million to us in the second quarter of 2024. We are also eligible to receive up to an additional $975.0 million in specified regulatory and sales-based milestones, and Sanofi will pay us tiered royalties ranging from low-teens to mid-twenties percent of Sanofi's and any of its affiliates' and sublicensees' annual net sales of losmapimod outside the United States. The royalties are payable on a product-by-product basis during a specified royalty term, and may be reduced in specified circumstances.

In addition to our product candidates, we developed a discovery approach that we employ to systematically identify and validate cellular drug targets that can potentially modulate gene expression to treat known root causes of genetically defined rare diseases. Our discovery approach led to the identification of both losmapimod for FSHD and pociredir for SCD, as well as a robust discovery pipeline.

Since inception, our operations have focused on organizing and staffing our company, business planning, raising capital, establishing our intellectual property, building our discovery platform, including our proprietary compound library and technologies, identifying drug targets and potential product candidates, in-licensing assets, producing drug substance and drug product material for use in clinical trials and conducting preclinical studies and clinical trials. To date, we have funded our operations primarily from the sale of shares of our capital stock and from upfront payments received under our collaboration and license agreements.

We have incurred significant operating losses since our inception, with the exception of the three and six months ended June 30, 2024, and we expect to continue to incur significant operating losses for the foreseeable future. Our ability to generate product revenue sufficient to achieve profitability, if ever, will depend heavily on the successful development and eventual commercialization of one or more of our product candidates. Our net income was $28.5 million for the six months ended June 30, 2024, primarily due to the $80.0 million of collaboration revenue associated with our collaboration and license agreement with Sanofi that we recognized during the

period. Our net loss was $48.6 million for the six months ended June 30, 2023. As of June 30, 2024, we had an accumulated deficit of $481.1 million. Excluding the potential for future milestone payments under our collaboration and license agreement with Sanofi, we expect our expenses and operating losses will increase substantially over the next several years in connection with our ongoing activities, as we:

- continue our clinical development of losmapimod and pociredir;
- continue our ongoing preclinical studies;
- advance clinical-stage product candidates into later stage trials such as REACH, the Phase 3 clinical trial of losmapimod for the treatment of FSHD;
- pursue the discovery of drug targets for other genetically-defined rare diseases and the subsequent development of any resulting product candidates, including for Diamond Blackfan Anemia, or DBA, under our license agreement with CAMP4;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- scale up our manufacturing processes and capabilities, or arrange for a third party to do so on our behalf, to support our clinical trials of our product candidates and commercialization of any of our product candidates for which we obtain marketing approval;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain regulatory approval and that we have not out-licensed;
- acquire or in-license products, product candidates, technologies and/or data referencing rights, such as our agreement with CAMP4;
- make any milestone payments to affiliates of GlaxoSmithKline plc, or GSK, under our right of reference and license agreement with GSK upon the achievement of specified clinical or regulatory milestones, or to CAMP4 under our license agreement with CAMP4;
- maintain, expand, enforce, defend and protect our intellectual property;
- hire additional clinical, quality control and scientific personnel; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts and our operations as a public company.

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 a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. 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, scale back or discontinue the development and commercialization of one or more of our product candidates, or grant rights to develop and market our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves.

Because of the numerous risks and uncertainties associated with drug development, we are unable to predict the timing or amount of increased expenses or the timing of 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, 2024, we had $273.8 million in cash, cash equivalents, and marketable securities. We believe that our existing cash, cash equivalents, and marketable securities as of June 30, 2024 will enable us to fund our operating expenses and capital expenditure requirements into 2027. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See “—Liquidity and Capital Resources.”

Components of Results of Operations

Revenue

We have not generated any revenue from product sales and do not expect to generate revenue from the sale of products for several years, if at all. If our development efforts for our current or future product candidates are successful and result in marketing approval, we may generate revenue in the future from product sales. We cannot predict if, when or to what extent we will generate

revenue from the commercialization and sale of our product candidates. We may never succeed in obtaining regulatory approval for any of our product candidates.

In May 2024, we entered into a collaboration and license agreement with Sanofi, pursuant to which we granted Sanofi an exclusive license under certain intellectual property rights to commercialize losmapimod, an oral small molecule for the treatment of FSHD outside of the United States.

During the three months ended June 30, 2024, we recognized $80.0 million of revenue associated with the upfront license payment. During the three months ended June 30, 2024, we recorded a $2.3 million reduction in research and development expenses in connection with global development activities for losmapimod. During the three months ended June 30, 2024, we recognized no revenue associated with the Sanofi territory-specific manufacturing activities for losmapimod.

In the future, we may generate revenue from services performed related to Sanofi territory-specific manufacturing for losmapimod, as well as from milestones and royalty payments under the Sanofi collaboration agreement. We expect that our revenue may fluctuate from quarter-to-quarter and year-to-year based on our performance of Sanofi territory-specific manufacturing services and as a result of the timing, amount, and achievement of milestones under the Sanofi collaboration agreement.

In July 2020, we entered into a collaboration and license agreement with MyoKardia, which we amended in April 2023 and again in July 2024, pursuant to which we granted to MyoKardia an exclusive worldwide license under certain intellectual property rights to research, develop, make, have made, use, have used, sell, have sold, offer for sale, have offered for sale, import, have imported, export, have exported, distribute, have distributed, market, have marketed, promote, have promoted, or otherwise exploit products directed against certain biological targets identified by us that are capable of modulating up to a certain number of genes of interest with relevance to certain genetically defined cardiomyopathies. MyoKardia was subsequently acquired by Bristol-Myers Squibb Company in November 2020. The primary goal of the collaboration is to identify and validate potential biological targets for further research, in order to support the development, manufacture and commercialization of product candidates by MyoKardia for the potential treatment of certain genetically defined cardiomyopathies. We satisfied our obligation to perform research services as of December 31, 2023.

Under the terms of the MyoKardia collaboration agreement, we received a $10.0 million upfront payment and a $2.5 million payment as prepaid research funding in July 2020. MyoKardia agreed to reimburse us for the costs of the research activities not covered by the prepaid research funding, up to a maximum amount of total research funding (including the prepaid research funding). Upon the achievement of specified preclinical, development and sales milestones, we will be entitled to preclinical milestone payments, development milestone payments and sales milestone payments of up to $298.5 million in the aggregate per target for certain potential cardiomyopathy gene targets, and of up to $150.0 million in the aggregate per target for certain other potential cardiomyopathy gene targets. To date, we have achieved a $2.5 million specified preclinical milestone. MyoKardia will also pay us tiered royalties ranging from a mid single-digit percentage to a low double-digit percentage based on MyoKardia's, and any of its affiliates' and sublicensees', annual worldwide net sales of products under the MyoKardia collaboration agreement directed against any identified target. The royalties are payable on a product-by-product basis during a specified royalty term, and may be reduced in specified circumstances.

For the three months ended June 30, 2024 and 2023, we recognized zero and $0.9 million, respectively, of collaboration revenue under the MyoKardia collaboration agreement. As of June 30, 2024 and December 31, 2023, we have recorded no deferred revenue associated with the MyoKardia collaboration agreement. As of June 30, 2024, we had received $7.7 million of cost reimbursement payments and $2.5 million of milestone payments under the MyoKardia collaboration agreement. As of June 30, 2024, we recorded no accounts receivable or unbilled accounts receivable under the MyoKardia collaboration agreement.

In the future, we may generate revenue from milestones and royalty payments under the MyoKardia collaboration agreement. We expect that our revenue may fluctuate from quarter-to-quarter and year-to-year as a result of the timing, amount, and achievement of milestones under the MyoKardia collaboration agreement.

We may also in the future enter into additional license or collaboration agreements for our product candidates or intellectual property, and we may generate revenue in the future from payments as a result of such license or collaboration agreements.

Operating Expenses

Research and Development Expenses

Research and development expenses represent costs incurred by us for the discovery, development, and manufacture of our product candidates and include:

- external research and development expenses incurred under agreements with contract research organizations, contract manufacturing organizations, and consultants;
- salaries, payroll taxes, employee benefits and stock-based compensation expenses for individuals involved in research and development efforts;
- laboratory supplies;
- costs related to compliance with regulatory requirements; and
- facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent, maintenance of facilities, insurance and other operating costs.

We expense research and development costs as incurred. We recognize expenses for certain development activities, such as clinical trials and manufacturing, based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment or other information provided to us by our vendors. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of expenses incurred. Non-refundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. These 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.

External costs represent a significant portion of our research and development expenses, which we track on a program-by-program basis following the nomination of a development candidate. Our internal research and development expenses consist primarily of personnel-related expenses, including stock-based compensation expense. We do not track our internal research and development expenses on a program-by-program basis as the resources are deployed across multiple projects.

The following table summarizes our external research and development expenses by program following nomination as a development candidate for the three and six months ended June 30, 2024 and 2023. Pre-development candidate expenses, unallocated expenses and internal research and development expenses are classified separately. Payments to or reimbursements from Sanofi related to global development activities are accounted for as an increase to or reduction of losmapimod external expenses.

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	**2024**	**2023**	**2024**	**2023**
Losmapimod external expenses	$ 6,181	$ 7,396	$ 14,475	$ 13,725
Pociredir external expenses	1,706	1,987	3,804	4,555
Pre-development candidate expenses and unallocated expenses	3,339	3,429	7,004	6,440
Internal research and development expenses	6,035	5,037	11,751	9,844
Total research and development expenses	$ 17,261	$ 17,849	$ 37,034	$ 34,564

The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing, and estimated costs of the efforts that will be necessary to complete the remainder of the development of our product candidates. We are also unable to predict when, if ever, material net cash inflows will commence from our product candidates, if approved. This is due to the numerous risks and uncertainties associated with developing our product candidates, including the uncertainty related to:

- the timing and progress of preclinical and clinical development activities;
- the number and scope of preclinical and clinical programs we decide to pursue;
- our ability to raise additional funds necessary to complete clinical development of and, if applicable, commercialize our product candidates if and when approved;
- our ability to maintain our current research and development programs and to establish new ones;

- our ability to establish new licensing or collaboration arrangements;
- the progress of the development efforts of parties with whom we may enter into 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 raw materials and active pharmaceutical ingredient, or API, for use in production of our product candidates;
- our ability to establish and operate a manufacturing facility, or secure manufacturing supply through relationships with third parties;
- our ability to consistently manufacture our product candidates in quantities sufficient for use in clinical trials;
- our ability to obtain and maintain intellectual property protection and regulatory exclusivity, both in the United States and internationally;
- our ability to maintain, enforce, defend and protect our rights in our intellectual property portfolio;
- our ability to obtain and maintain third-party coverage and adequate reimbursement for our product candidates, if approved;
- the acceptance of our product candidates, if approved, by patients, the medical community and third-party payors;
- competition with other products; and
- a continued acceptable safety profile of our products following receipt of any regulatory approvals.

A change in the outcome of any of these variables with respect to the development of any of our product candidates would significantly change the costs and timing associated with the development of that product candidate, and potentially other candidates.

Research and development activities account for a significant portion of our operating expenses. We expect our research and development expenses to increase significantly in future periods as we continue to implement our business strategy, which includes advancing losmapimod for the treatment of FSHD, advancing pociredir for the treatment of SCD, expanding our research and development efforts, including hiring additional personnel to support our research and development efforts, and seeking regulatory approvals for our product candidates that successfully complete clinical trials. In addition, product candidates in later stages of clinical development generally incur higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. As a result, we expect our research and development expenses to increase as our product candidates advance into later stages of clinical development. However, we do not believe that it is possible at this time to accurately project total program-specific expenses through approval and commercialization. There are numerous factors associated with obtaining regulatory approval and the successful commercialization of any of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development.

General and Administrative Expenses

General and administrative expenses consist of personnel-related costs, including salaries, benefits and stock-based compensation expense, for our personnel in executive, finance and accounting, human resources, business operations and other administrative functions, legal fees related to patent, intellectual property and corporate matters, fees paid for accounting and tax services, consulting fees and facility-related costs not otherwise included in research and development expenses.

We expect that our general and administrative expenses will increase in the future to support continued research and development activities and planned commercialization activities in the United States, including establishing a sales, marketing and distribution infrastructure to commercialize any medicines for which we may obtain marketing approval. These increases will likely include increased costs related to the hiring of additional personnel, legal, audit, filing fees, and general compliance and consulting expenses, among other expenses.

Other Income, Net

Other income, net consists primarily of interest income related to our investments in cash equivalents and marketable securities.

Results of Operations

Comparison of the Three Months ended June 30, 2024 and 2023

The following summarizes our results of operations for the three months ended June 30, 2024 and 2023 along with the changes in those items in dollars:

(in thousands)	Three Months Ended June 30, 2024	2023	Change $
Collaboration revenue	$ 80,000	$ 880	$ 79,120
Operating expenses:			
Research and development	17,261	17,849	(588)
General and administrative	10,247	10,323	(76)
Total operating expenses	27,508	28,172	(664)
Income (loss) from operations	52,492	(27,292)	79,784
Other income, net	2,917	3,509	(592)
Net income (loss)	$ 55,409	$ (23,783)	$ 79,192

Collaboration Revenue

Collaboration revenue increased by $79.1 million from $0.9 million for the three months ended June 30, 2023 to $80.0 million for the three months ended June 30, 2024. The increase was primarily attributable to the recognition of $80.0 million of revenue associated with the upfront license payment received during the second quarter of 2024 under the Sanofi collaboration agreement.

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended June 30, 2024 and 2023:

(in thousands)	Three Months Ended June 30, 2024	2023	Change $
External research and development	$ 9,591	$ 10,353	$ (762)
Employee compensation	6,035	5,037	998
Laboratory supplies	415	987	(572)
Facility costs	1,058	1,128	(70)
Other	162	344	(182)
Total research and development expenses	$ 17,261	$ 17,849	$ (588)

Research and development expense decreased by $0.5 million from $17.8 million for the three months ended June 30, 2023 to $17.3 million for the three months ended June 30, 2024. The decrease in research and development expense was primarily attributable to the following:

- $0.8 million of decreased external research and development costs, primarily due to $2.3 million of reimbursement from the global development cost sharing under our collaboration with Sanofi for losmapimod, partially offset by increased development costs associated with the advancement of REACH, as we completed enrollment in September 2023;
- $0.6 million of decreased laboratory supplies costs;
- $0.1 million of decreased facility costs; and
- $0.2 million of decreased other costs;
- partially offset by $1.0 million of increased employee compensation costs, including a $0.7 million increase in stock-based compensation expense.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the three months ended June 30, 2024 and 2023:

(in thousands)	Three Months Ended June 30, 2024	2023	Change $
Employee compensation	$ 5,482	$ 5,710	$ (228)
Professional services	3,612	3,137	475
Facility costs	271	616	(345)
Other	882	860	22
Total general and administrative expenses	$ 10,247	$ 10,323	$ (76)

General and administrative expenses decreased by $0.1 million from $10.3 million for the three months ended June 30, 2023 to $10.2 million for the three months ended June 30, 2024. The decrease in general and administrative expenses was primarily attributable to the following:

- $0.3 million of decreased facility costs as a result of the expiration of our lease agreement for office space at 125 Sidney Street;
- $0.2 million of decreased employee compensation costs due to decreased headcount, which reflects a partial offset of $0.3 million increase in stock-based compensation expense;
- partially offset by $0.5 million of increased professional services costs, primarily due to increased legal costs.

Other Income, Net

Other income, net decreased by $0.6 million from $3.5 million for the three months ended June 30, 2023 to $2.9 million for the three months ended June 30, 2024. The decrease was primarily attributable to a decrease in our average cash, cash equivalents, and marketable securities balance.

Comparison of the Six Months ended June 30, 2024 and 2023

The following summarizes our results of operations for the six months ended June 30, 2024 and 2023 along with the changes in those items in dollars:

(in thousands)	Six Months Ended June 30, 2024	2023	Change $
Collaboration revenue	$ 80,000	$ 1,175	$ 78,825
Operating expenses:			
Research and development	37,034	34,564	2,470
General and administrative	20,308	21,843	(1,535)
Total operating expenses	57,342	56,407	935
Loss from operations	22,658	(55,232)	77,890
Other income, net	5,881	6,670	(789)
Net loss	$ 28,539	$ (48,562)	$ 77,101

Collaboration Revenue

Collaboration revenue increased by $78.8 million from $1.2 million for the six months ended June 30, 2023 to $80.0 million for the six months ended June 30, 2024. The increase was primarily attributable to the recognition of $80.0 million of revenue associated with the upfront license payment received during the second quarter of 2024 under the Sanofi collaboration agreement.

Research and Development Expenses

The following table summarizes our research and development expenses for the six months ended June 30, 2024 and 2023:

(in thousands)	Six Months Ended June 30, 2024	2023	Change $
External research and development	$ 21,801	$ 19,903	$ 1,898
Employee compensation	11,751	9,844	1,907
Laboratory supplies	818	1,698	(880)
Facility costs	2,177	2,311	(134)
Other	487	808	(321)
Total research and development expenses	$ 37,034	$ 34,564	$ 2,470

Research and development expense increased by $2.4 million from $34.6 million for the six months ended June 30, 2023 to $37.0 million for the six months ended June 30, 2024. The increase in research and development expense was primarily attributable to the following:

- $1.9 million of increased employee compensation costs, including a $1.2 million increase in stock-based compensation expense;
- $1.9 million of increased external research and development costs, primarily due to the advancement of REACH as we completed enrollment in September 2023, partially offset by $2.3 million reimbursement from the global development cost sharing under our collaboration with Sanofi for losmapimod;
- partially offset by $0.9 million of decreased laboratory supplies costs;
- $0.1 million of decreased facility costs; and
- $0.3 million of decreased other costs.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the six months ended June 30, 2024 and 2023:

(in thousands)	Six Months Ended June 30, 2024	2023	Change $
Employee compensation	$ 11,144	$ 12,977	$ (1,833)
Professional services	6,618	5,955	663
Facility costs	870	1,273	(403)
Other	1,676	1,638	38
Total general and administrative expenses	$ 20,308	$ 21,843	$ (1,535)

General and administrative expenses decreased by $1.5 million from $21.8 million for the three months ended June 30, 2023 to $20.3 million for the six months ended June 30, 2024. The decrease in general and administrative expenses was primarily attributable to the following:

- $1.8 million of decreased employee compensation costs, which reflects a $0.5 million decrease in stock-based compensation expense, due to decreased headcount;
- $0.4 million of decreased facility costs as a result of the expiration of our lease agreement for office space at 125 Sidney Street;
- partially offset by $0.7 million of increased professional services costs, primarily due to increased legal costs.

Other Income, Net

Other income, net decreased by $0.8 million from $6.7 million for the six months ended June 30, 2023 to $5.9 million for the six months ended June 30, 2024. The decrease was primarily attributable to a decrease in our average cash, cash equivalents, and marketable securities balance.

Liquidity and Capital Resources

Sources of Liquidity

We have incurred significant operating losses since our inception and expect to continue to incur significant operating losses for the foreseeable future and may never become profitable. We have not yet commercialized any of our product candidates, which are in various phases of preclinical and clinical development, and we do not expect to generate revenue from sales of any products for several years, if at all. As of June 30, 2024, we have funded our operations primarily with aggregate gross proceeds of $792.5 million from the sale of shares of our capital stock and from upfront payments received under our collaboration and license agreements. As of June 30, 2024, we had cash, cash equivalents, and marketable securities of $273.8 million.

In February 2024, we entered into a controlled equity offering[SM] agreement with Cantor Fitzgerald & Co. and Stifel, Nicolaus & Company, Incorporated, as agents, with respect to an at-the-market offering program pursuant to which we may offer and sell, from time to time in our sole discretion, shares of our common stock, par value $0.001 per share, having an aggregate offering price of up to $100.0 million through the agents. As of June 30, 2024, we have not issued or sold any shares of common stock under the at-the-market offering program.

Cash Flows

The following table provides information regarding our cash flows for the six months ended June 30, 2024:

	Six Months Ended June 30,	
(in thousands)	**2024**	**2023**
Net cash provided by (used in) operating activities	$ 33,615	$ (44,901)
Net cash provided by (used in) investing activities	25,620	(74,066)
Net cash provided by financing activities	2,028	117,835
Net increase (decrease) in cash, cash equivalents, and restricted cash	$ 61,263	$ (1,132)

Net Cash Provided by (Used in) Operating Activities

Net cash provided by operating activities was $33.6 million during the six months ended June 30, 2024 compared to net cash used in operating activities of $44.9 million during the six months ended June 30, 2023. The increase in net cash provided by operating activities of $78.5 million was primarily due to the receipt of the $80.0 million upfront license payment during the second quarter of 2024 under the Sanofi collaboration agreement, partially offset by an increase in our net loss, including as a result of increased external research and development costs as we continued the advancement of REACH.

Net Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities was $25.6 million during the six months ended June 30, 2024 compared to net cash used in investing activities of $74.1 million during the six months ended June 30, 2023. The increase in net cash provided by investing activities of $99.7 million was primarily due to net maturities of marketable securities during the six months ended June 30, 2024, as compared to net purchases of marketable securities during the six months ended June 30, 2023.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $2.0 million during the six months ended June 30, 2024 compared to net cash provided by financing activities of $117.8 million during the six months ended June 30, 2023. Net cash provided by financing activities during the six months ended June 30, 2024 consisted of net proceeds of $1.8 million from the issuance of common stock under our benefit plans. Net cash provided by financing activities during the six months ended June 30, 2023 primarily consisted of net proceeds of $117.3 million from the January 2023 public offering of our common stock.

Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing research and development activities, particularly as we continue the research and development of, initiate clinical trials of, and seek marketing approval for, our product candidates. In addition, we expect to incur additional costs to support the growth of our organization. As a result, we expect to incur substantial operating losses and negative operating cash flows for the foreseeable future, excluding the potential for future milestone payments under our collaboration and license agreement with Sanofi.

Based on our current operating plan, we believe that our existing cash, cash equivalents, and marketable securities as of June 30, 2024 will enable us to fund our operating expenses and capital expenditure requirements into 2027. However, we have based this estimate on assumptions that may prove to be wrong and we could exhaust our capital resources sooner than we expect.

Our funding requirements and timing and amount of our operating expenditures will depend largely on:

- the progress, costs and results of our clinical trials of losmapimod and pociredir;
- the scope, progress, costs and results of discovery research, preclinical development, laboratory testing and clinical trials for our current product candidates in additional indications or for any future product candidates that we may pursue, including under our license agreement with CAMP4;
- the number of and development requirements for other product candidates that we pursue;
- the costs, timing and outcome of regulatory review of our product candidates;
- our ability to enter into contract manufacturing arrangements for supply of API and manufacture of our product candidates and the terms of such arrangements;
- the success of our recent collaboration and license agreement with Sanofi and our collaboration with MyoKardia;
- our ability to establish and maintain additional strategic collaborations, licensing or other arrangements and the financial terms of such arrangements;
- the payment or receipt of milestones, royalties and other collaboration-based revenues, if any;
- the costs and timing of future commercialization activities, including product manufacturing, sales, marketing and distribution, for any of our product candidates for which we may receive marketing approval and that we do not out-license to a third party;
- the amount and timing of revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property and proprietary rights and defending any intellectual property-related claims; and
- the extent to which we acquire or in-license other products, product candidates, technologies or data referencing rights.

A change in the outcome of any of these or other variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. We will need to continue to rely on additional financing to achieve our business objectives.

In addition to the variables described above, if and when any of our product candidates successfully complete development, we will incur substantial additional costs associated with regulatory filings, marketing approval, post-marketing requirements, maintaining our intellectual property rights, and regulatory protection, in addition to other commercial costs. We cannot reasonably estimate these costs at this time.

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, collaboration arrangements, strategic alliances and marketing, distribution or licensing arrangements. We currently have no credit facility or committed sources of capital. To the extent that we raise additional capital through the future sale of equity securities, the ownership interests of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing common stockholders. If we raise additional funds through the issuance of debt securities, these securities could contain covenants that would restrict our operations. We may require additional capital beyond our currently anticipated amounts, and additional capital may not be available on reasonable terms, or at all. If we raise additional funds through collaboration arrangements, strategic alliances or marketing, distribution or licensing arrangements in the future, we may have to relinquish valuable rights to our technologies, future revenue streams 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 when needed, we may be required to delay, limit, reduce or terminate development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of these consolidated financial statements requires us to make judgments and estimates that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of expenses during the reporting periods. Our estimates are based on our historical experience, known trends and events, and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities and amount of expense recognized that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We evaluate our estimates and assumptions on an ongoing basis. The effects of material revisions in estimates, if any, will be reflected in the consolidated financial statements prospectively from the date of change in estimates. During the three months ended June 30, 2024, there were no material changes to our critical accounting policies from those described in our Annual Report on Form 10-K filed with the SEC on February 27, 2024, except as noted below with respect to our accounting policies related to collaboration revenue.

Collaborative Arrangements

At contract inception, we analyze our collaboration arrangements to assess whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and are exposed to significant risks and rewards dependent on the commercial success of such activities, and therefore within the scope of ASC Topic 808, *Collaborative Arrangements* (ASC 808). This assessment is performed on an ongoing basis throughout the collaboration based on changes in the responsibilities of the parties in the arrangement. For collaboration arrangements within the scope of ASC 808 that contain multiple elements, we first determine which elements of the collaboration are deemed to be within the scope of ASC 808 and which elements of the collaboration are more reflective of a vendor-customer relationship and are therefore within the scope of ASC 606, *Revenue from Contracts with Customers* (ASC 606).

For elements of collaboration arrangements that are accounted for pursuant to ASC 808, an appropriate recognition method is determined and applied consistently, either by analogy to authoritative accounting literature or by applying a reasonable and rational policy election. We evaluate the income statement classification for presentation of amounts due from or owed to collaborators associated with multiple activities in a collaboration arrangement based on the nature of each separate activity. We have made an accounting policy election to account for research and development reimbursements received from our collaboration partner that are outside of the scope of ASC 606 as a reduction of research and development expenses to best reflect the economics and nature of the transaction in the context of the unit-of-account.

See Note 2, "Summary of Significant Accounting Policies", in our audited consolidated financial statements for the year ended December 31, 2023 included in our Annual Report on Form 10-K for our accounting policies for arrangements within the scope of ASC 606.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

Emerging Growth Company Status

The Jumpstart Our Business Startups Act of 2012 permits an "emerging growth company" such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected not to "opt out" of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that we either (i) irrevocably elect to "opt out" of such extended transition period or (ii) no longer qualify as an emerging growth company.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company, as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, for this reporting period and are not required to provide the information required under this item.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer (our principal executive officer) and our Chief Financial Officer (our principal financial officer), evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2024. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2024, our Chief Executive Officer and our Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

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

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

On April 28, 2023, a class action complaint was filed in the United States District Court for the District of New Jersey against our company and current and former officers, or the Securities Action. On May 19, 2023, the Securities Action was transferred to the United States District Court for the District of Massachusetts, captioned *Celano v. Fulcrum Therapeutics, Inc*., et al., Case No. 1:23-cv-11125-IT. On July 31, 2023, the court appointed a lead plaintiff, who filed an amended complaint on September 29, 2023. The Securities Action alleges violations of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder against all defendants and control person violations of Section 20(a) against the individuals, related to our February 2023 announcement that the FDA issued a clinical hold regarding the IND application for pociredir for the potential treatment of SCD. The Securities Action alleges that the defendants made misleading statements and omitted to disclose material information related to the clinical hold and seeks, among other things, compensatory damages in connection with an allegedly inflated stock price between March 3, 2022, and March 8, 2023, as well as attorneys' fees and costs. On November 28, 2023, all defendants filed a motion to dismiss the Securities Action. Briefing was completed on the motion in February 2024, and the motion is currently pending. We intend to defend vigorously against this litigation.

Item 1A. Risk Factors.

Our future operating results could differ materially from the results described in this Quarterly Report on Form 10-Q due to the risks and uncertainties described below. You should consider carefully the following information about risks below in evaluating our business. If any of the following risks actually occur, our business, financial conditions, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock would likely decline. In addition, we cannot assure investors that our assumptions and expectations will prove to be correct. Important factors could cause our actual results to differ materially from those indicated or implied by forward-looking statements. See "Cautionary Note Regarding Forward-Looking Statements" on page i of this Quarterly Report on Form 10-Q for a discussion of some of the forward-looking statements that are qualified by these risk factors. Factors that could cause or contribute to such differences include those factors discussed below.

Risks Related to our Financial Position and Need for Additional Capital

We have incurred significant losses since our inception. Excluding the potential for future milestone payments under our collaboration and license agreement with Sanofi, we expect to incur losses over the next several years and may never achieve or maintain profitability.

Since inception, we have incurred significant operating losses. Our net loss was $97.3 million for the year ended December 31, 2023. Our net income was $28.5 million for the six months ended June 30, 2024 primarily due to the recognition of $80.0 million of collaboration revenue associated with our collaboration and license agreement with Sanofi. As of June 30, 2024, we had an accumulated deficit of $481.1 million. To date, we have funded our operations primarily from the sale of shares of our capital stock and from upfront payments received under our collaboration and license agreements. We have devoted substantially all of our financial resources and efforts to research and development, including clinical trials and preclinical studies. We are still in the early stages of development of our product candidates, and we have not completed development of any product candidates. We expect to continue to incur significant expenses and operating losses over the next several years. Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially as we:

- continue our clinical development of losmapimod and pociredir;
- continue our ongoing preclinical studies;
- advance clinical-stage product candidates through later stage trials, such as REACH, the Phase 3 clinical trial of losmapimod for the treatment of FSHD;
- pursue the discovery of drug targets for other genetically-defined rare diseases and the subsequent development of any resulting product candidates, including for DBA under our license agreement with CAMP4;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- scale up our manufacturing processes and capabilities, or arrange for a third party to do so on our behalf, to support our clinical trials of our product candidates and commercialization of any of our product candidates for which we may obtain marketing approval;

- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain regulatory approval and that we have not out-licensed;
- acquire or in-license products, product candidates, technologies and/or data referencing rights, such as our agreement with CAMP4;
- make any milestone payments to affiliates of GSK under our right of reference and license agreement with GSK upon the achievement of specified clinical or regulatory milestones, or to CAMP4 under our license agreement with CAMP4;
- maintain, expand, enforce, defend and protect our intellectual property;
- hire additional clinical, quality control and scientific personnel; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts and our operations as a public company.

To become and remain profitable, we must succeed in developing, and eventually commercializing, a product or products that generate significant revenue. The ability to achieve this success will require us to be effective in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates, discovering additional product candidates, obtaining regulatory approval for these product candidates and manufacturing, marketing and selling any products for which we may obtain regulatory approval. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Our expenses will increase if, among other things:

- we are required by the FDA, the EMA, or other regulatory authorities to perform trials or studies in addition to, or different than, those expected;
- there are any further delays in completing our ongoing clinical trials or otherwise in the development of any of our current or future product candidates, such as due to any further clinical holds imposed by the FDA (similar to the hold on the IND application for pociredir in SCD that was lifted in August 2023), or due to enrollment challenges (such as for our ongoing clinical trial of pociredir in light of the more stringent inclusion and exclusion criteria); or
- there are any third-party challenges to our intellectual property or we need to defend against any intellectual property-related claim.

Even 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 depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our pipeline of product candidates or even continue our operations. A decline in the value of our company could also cause our stockholders to lose all or part of their investment.

We will need substantial additional funding. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

We expect to devote substantial financial resources to our ongoing and planned activities, particularly as we continue our ongoing and planned clinical trials of losmapimod and pociredir, continue research and development and initiate additional clinical trials of, and seek regulatory approval for, these and other product candidates. We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance our preclinical activities and clinical trials. In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution, particularly if we do not out-license our product candidate. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. Given current uncertainty in the capital markets and other factors, such funding may not be available on terms favorable to us or at all. If we are unable to raise capital when needed or on acceptable terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

Our future capital requirements will depend on many factors, including:

- the progress, costs and results of our ongoing clinical trials of losmapimod, including REACH, the Phase 3 clinical trial of losmapimod for the treatment of FSHD, which completed enrollment in September 2023, and our Phase 1b clinical trial of pociredir in SCD;
- additional planned clinical trials;
- the scope, progress, costs and results of discovery research, preclinical development, laboratory testing and clinical trials for our current product candidates in additional indications or for any future product candidates that we may pursue;
- the number of and development requirements for other product candidates that we pursue;

- the costs, timing and outcome of regulatory review of our product candidates;
- our ability to enter into contract manufacturing arrangements for supply of API and manufacture of our product candidates and the terms of such arrangements;
- the success of our collaborations with Sanofi and MyoKardia or under our license agreement with CAMP4;
- our ability to establish and maintain additional strategic collaborations, licensing or other arrangements and the financial terms of such arrangements;
- the payment or receipt of milestones, royalties and other collaboration-based revenues, if any;
- the costs and timing of future commercialization activities, including product manufacturing, sales, marketing and distribution, for any of our product candidates for which we may receive marketing approval and that we do not out-license for commercialization;
- the amount and timing of revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property and proprietary rights and defending any intellectual property-related claims; and
- the extent to which we acquire or in-license other products, product candidates, technologies or data referencing rights.

As of June 30, 2024, we had cash, cash equivalents, and marketable securities of approximately $273.8 million. We believe that our cash, cash equivalents, and marketable securities as of June 30, 2024 will enable us to fund our operating expenses and capital expenditure requirements into 2027. However, we have based this estimate on assumptions that may prove to be wrong, and our operating plan may change as a result of many factors currently unknown to us. As a result, we could deplete our capital resources sooner than we currently expect.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Commercial revenues, if any, will not be derived unless and until we can achieve sales of products, which we do not anticipate for several years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all, and may become even more difficult to obtain due to rising interest rates and the recent downturn in the U.S. capital markets and the biotechnology sector in general. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for one or more of our product candidates or discovery stage programs or delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to bring our product candidates to market. We may also choose to further realign our operations to achieve additional operational efficiencies beyond the strategic realignment effected in 2022.

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

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights as common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, selling or licensing our assets, making capital expenditures or declaring dividends.

If we raise additional 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 when needed, we may be required to delay, limit, reduce or terminate 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.

We have in the past relied, and in the future anticipate we will rely, in part on sales of our common stock through an at-the-market, or ATM, offering program. Increased volatility and decreases in market prices of equity securities generally and of our

common stock in particular may have an adverse impact on our willingness and/or ability to continue to sell our common stock through our ATM offering program. Decreases in these sales could affect the cost or availability of equity capital, which could in turn have an adverse effect on our business, including current operations, future growth, revenues, net income and the market prices of our common stock.

In February 2024, we established a new ATM offering program to sell shares of our common stock having an aggregate offering price of up to $100.0 million from time to time. Given the overall volatility in the capital markets, we may not be willing or able to continue to raise equity capital through our ATM offering program. We may, therefore, need to turn to other sources of funding that may have terms that are not favorable to us, or reduce our business operations given capital constraints.

Alternative financing arrangements could involve issuances of one or more types of securities, including common stock, preferred stock, convertible debt, warrants to acquire common stock or other securities. These securities could be issued at or below the then prevailing market price for our common stock. In addition, if we issue debt securities, the holders of the debt would have a claim to our assets that would be superior to the rights of stockholders until the principal, accrued and unpaid interest and any premium or make-whole has been paid. In addition, if we borrow funds and/or issue debt securities through a subsidiary, the lenders and/or holders of those debt securities would have a right to payment that would be effectively senior to our equity ownership in the subsidiary, which would adversely affect the rights of holders of both our equity securities and, if any, our debt and debt securities.

Interest on any newly-issued debt securities and/or newly-incurred borrowings would increase our operating costs and reduce our net income, and these impacts may be material. If the issuance of new securities results in diminished rights to holders of our common stock, the market price of our common stock could be materially and adversely affected. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, the consequences could result in a material adverse effect on our business, operating results, financial condition and prospects.

Our operations have been focused on research and development and conducting clinical trials, which may make it difficult for stockholders to evaluate the success of our business to date and to assess our future viability.

We commenced activities in 2015 and are a clinical-stage biotechnology company. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, establishing our intellectual property, building our discovery platform, identifying drug targets and potential product candidates, in-licensing assets, producing drug substance and drug product material for use in clinical trials and conducting preclinical studies and clinical trials. We have not yet demonstrated our ability to successfully develop any product candidate, obtain regulatory approvals, manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization or arrange for a third party to do so on our behalf. Consequently, any predictions stockholders make about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing products.

In addition, as our business grows, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We expect our financial condition and operating results to fluctuate significantly from quarter-to-quarter and year-to-year due to a variety of factors, many of which are beyond our control. Accordingly, stockholders should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

Our business was negatively impacted by the COVID-19 pandemic and may in the future be impacted by any future pandemics. In addition, the effects of any future pandemics may adversely impact economies worldwide, which could result in adverse effects on our business and operations.

We experienced enrollment delays in our ReDUX4 clinical trial due to the COVID-19 pandemic as the clinical trial sites for our ReDUX4 clinical trial temporarily postponed trial-related activities. We also saw temporary disruptions in other business activities due to a temporary reduction in workforce presence at our Cambridge research facility, and COVID-19 had a significant impact on economies worldwide. Future pandemics may arise, and they, like COVID-19, could impact our company, our CMOs and contract research organizations, or CROs, creating disruptions that affect our ability to initiate and complete preclinical studies or clinical trials, disrupt our supply chain for our research and development activities, and disrupt any then planned or ongoing clinical trials for any number of reasons. Any future pandemics could similarly impact patient recruitment or retention for clinical trials, or result in resources being redirected in a way that adversely impacts our ability to progress regulatory approvals and protect our intellectual

property. In addition, as with COVID-19 pandemic, we may face impediments to regulatory meetings and approvals due to recommended safety measures intended to limit in-person interactions in any future pandemic.

The COVID-19 pandemic caused significant disruptions in the financial markets and any future pandemic could similarly cause such disruptions, which could impact our ability to raise additional funds through public offerings and may also impact the volatility of our stock price and trading in our stock. We cannot be certain what the overall impact of any future pandemic will be on our business. The extent of the impact of any future pandemic on our business, financial condition, results of operations and prospects will depend on future developments that are uncertain.

Changes in tax laws or in their implementation or interpretation may 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), including with respect to net operating losses and research and development tax credits, could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. For example, under Section 174 of the U.S. Internal Revenue Code of 1986, as amended, or the Code, in taxable years beginning after December 31, 2021, expenses that are incurred for research and development in the United States will be capitalized and amortized, which may have an adverse effect on our cash flow. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. We urge investors to consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our common stock.

Our ability to use our net operating losses and research and development tax credit carryforwards to offset future taxable income may be subject to certain limitations.

As of December 31, 2023, we had federal and state net operating loss carryforwards of $312.3 million and $317.1 million, respectively, which begin to expire in 2036. Approximately $288.7 million of the federal net operating losses can be carried forward indefinitely. As of December 31, 2023, we also had federal orphan drug credits of $23.8 million, which begin to expire in 2040. As of December 31, 2023, we also had federal and state research and development tax credit carryforwards of $7.6 million and $4.9 million, respectively, which begin to expire in 2035 and 2030, respectively. These net operating loss and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities.

In general, under Section 382 of the Code, and corresponding provisions of state law, a corporation that undergoes an “ownership change,” which is generally defined as a greater than 50% change, by value, in its equity ownership by certain stockholders over a three-year period, is subject to limitations on its ability to utilize its pre-change net operating losses and research and development tax credit carryforwards to offset future taxable income. We conducted an analysis under Section 382 of the Code to determine if historical changes in ownership through December 31, 2021 would limit or otherwise restrict our ability to utilize our pre-change net operating losses and research and development tax credit carryforwards to offset future taxable income. As a result of the analysis, we do not believe that there are any significant limitations on our ability to utilize our net operating losses and research and development tax credit carryforwards to offset future taxable income. However, we may experience such ownership changes in the future (which may be outside our control). As a result, if, and to the extent that, we earn net taxable income, our ability to use our pre-change net operating losses and research and development tax credit carryforwards to offset such taxable income may be subject to limitations. Our net operating losses or credits may also be impaired under state law.

We have a history of cumulative losses and anticipate that we will continue to incur significant losses in the foreseeable future; thus, we do not know whether or when we will generate taxable income necessary to utilize our net operating losses or research and development tax credit carryforwards.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults or non-performance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations and financial condition and results of operations.

Events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. In March 2023, a number of banks (e.g., Silicon Valley Bank, Signature Bank and Silvergate Capital Corp.) were placed into receivership, followed by First Republic Bank in May 2023. Although the Federal Deposit Insurance Corporation, or FDIC, and others have taken steps to reduce risk to uninsured depositors, borrowers under credit agreements, letters of credit and certain other financial instruments with such banks or any other financial institution that is placed into receivership by the FDIC may be unable to access undrawn amounts thereunder. Even though we assess our banking relationships as we believe necessary or

appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors affecting the financial services industry or economy in general, such as these recent bank failures. These factors could also include, among others, liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry and the supervision thereof. In addition, investor concerns regarding the United States or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our contractual obligations or result in violations of federal or state wage and hour laws, which could have material adverse effect on our liquidity and on our business, financial condition or results of operations.

Risks Related to the Discovery and Development of our Product Candidates

We are early in our development efforts, and we only have two clinical-stage product candidates. If we are unable to commercialize directly or out-license to a third party our product candidates or experience significant delays in doing so, our business will be materially harmed.

We are early in our development efforts, and we have advanced only two product candidates into clinical trials, losmapimod for the treatment of FSHD, and pociredir for the treatment of SCD (which was on clinical hold between February and August 2023). We have invested substantially all of our efforts and financial resources in identifying and validating and conducting clinical trials on cellular drug targets that can potentially modulate gene expression to address the root cause of genetically-defined rare diseases. Our ability to generate product revenues, which we do not expect will occur for several years, if ever, will depend heavily on the successful development, regulatory approval and eventual commercialization of our product candidates. The success of our product candidates will depend on several factors, including the following:

- successfully completing preclinical studies and clinical trials;
- allowance by the FDA or other regulatory agencies of the INDs, clinical trial applications, or CTAs, or other regulatory filings for losmapimod, pociredir and future product candidates;
- expanding and maintaining a workforce of experienced scientists and others to continue to develop our product candidates;
- applying for and receiving marketing approvals from applicable regulatory authorities;
- obtaining and maintaining intellectual property protection and regulatory exclusivity for our product candidates;
- making arrangements with third-party manufacturers for, or establishing, commercial manufacturing capabilities;
- establishing sales, marketing and distribution capabilities and successfully launching commercial sales of the products, if and when approved, whether alone or in collaboration with others;
- acceptance of the products, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- obtaining and maintaining coverage, adequate pricing and adequate reimbursement from third-party payors, including government payors;
- maintaining, enforcing, defending and protecting our rights in our intellectual property portfolio;
- not infringing, misappropriating or otherwise violating others' intellectual property or proprietary rights; and
- maintaining a continued acceptable safety profile of the products following receipt of any regulatory approvals.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully develop and commercialize our product candidates, which would materially harm our business.

We may not be successful in our efforts to build a pipeline of product candidates.

Our current strategy is focused on developing small molecules to improve the lives of patients with genetically defined rare diseases. Even if we are successful in identifying drug targets and potential product candidates, such candidates that we identify may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to receive marketing approval and achieve market acceptance. Identifying, developing, obtaining regulatory approval for and commercializing additional product candidates will require substantial additional funding and is prone to the risks of failure inherent in product development. We cannot provide stockholders any assurance that we will be able to successfully identify additional product candidates, including as a result of our collaboration with MyoKardia, advance any additional product candidates through the development process or successfully commercialize any such additional product candidates.

Regulatory authorities have substantial discretion in the approval process and may cause delays in the approval or rejection of an application. As a result of these factors, it is difficult for us to predict the time and cost of product candidate development. There can be no assurance that any development problems we experience in the future related to our discovery technologies or any of our research or development programs will not cause significant delays or unanticipated costs, or that such development problems can be solved. If we do not successfully identify, develop, obtain regulatory approval for and commercialize product candidates, we will not be able to generate product revenues.

Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. The results of preclinical studies and early clinical trials may not be predictive of future results. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

We have two product candidates in clinical development. The risk of failure for each of our product candidates is high. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. We have not yet completed a pivotal clinical trial of any product candidate. Clinical trials may fail to demonstrate that our product candidates are safe for humans and effective for indicated uses. For example, pociredir, our clinical trial stage candidate to treat SCD, is an embryonic ectoderm development, or EED, inhibitor. EED is a member of the PRC2 complex, which also includes EZH2. There are approved products in the EZH2 class of medications and their approved labeling outlines safety risks, including an increased risk of malignancies. In the event that pociredir has similar safety risks as other PRC2 medications, this could impact its acceptance. Even if the clinical trials are successful, changes in marketing approval policies during the development period, changes in or the enactment or promulgation of additional statutes, regulations or guidance or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application.

Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support our planned INDs and other regulatory filings in the United States and abroad. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA or other regulatory agencies will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of our current or future product candidates. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin or continue. For example, in February 2023, the FDA imposed a clinical hold on our IND for pociredir in SCD. We worked diligently to resolve the hold as soon as possible, and in August 2023, the FDA lifted the clinical hold. Product candidates are subject to continued preclinical safety studies, which may be conducted concurrent with our clinical testing. The outcomes of these safety studies may delay the launch of or enrollment in future clinical trials and could impact our ability to continue to conduct our clinical trials.

Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, or at all. For example, we revised the inclusion and exclusion criteria of our clinical trial of pociredir in SCD to address the clinical hold imposed by the FDA, and are experiencing some difficulty enrolling patients who meet the updated more stringent criteria. While we are expanding our clinical trial sites, including outside the United States, to identify suitable patients that meet the new criteria, there can be no certainty as to whether we will be successful in completing the clinical trial with its revised design. A failure of one or more clinical trials can occur at any stage of testing, which may result from a multitude of factors, including, but not limited to, flaws in study design, dose selection issues, placebo effects, patient enrollment criteria and failure to demonstrate favorable safety or efficacy traits. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and preliminary or interim results of a clinical trial do not necessarily predict final results. For example, our product candidates may fail to show the desired safety and efficacy in clinical development despite positive results in preclinical studies or having successfully advanced through initial clinical trials. A lack of clinical benefit may be due to insufficient dosing or for other reasons. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical testing and earlier-stage clinical trials, and we cannot be certain that we will not face similar setbacks. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. Furthermore, the failure of any of our product candidates to demonstrate safety and efficacy in any clinical trial could negatively impact the perception of our other product candidates and/or cause the FDA or other regulatory authorities to require additional testing before approving any of our product candidates.

As described in Item 1 “Business—Licenses and Collaboration--Right of Reference and License Agreement with GlaxoSmithKline” in our Annual Report on Form 10-K for the year ended December 31, 2023, or the 2023 Annual Report, we have entered into a right of reference and license agreement, as amended, with affiliates of GSK. Although losmapimod was originally evaluated by GSK in nearly 3,600 subjects, GSK did not evaluate losmapimod in FSHD or in any other muscular dystrophy, and most of the subjects in these trials were given a dose that was lower than our planned dosage of 15 mg of losmapimod twice per day.

Accordingly, the safety data generated from GSK's clinical trials of losmapimod may not be predictive or indicative of the results of our clinical trials. Similarly, while we believe the safety data from GSK's clinical trials may, in part, support the safety database for losmapimod, GSK evaluated a limited number of subjects at a dose of 15 mg twice daily.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- regulators or institutional review boards, or IRBs, may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- regulators may decide the design of our clinical trials is flawed, for example if our trial protocol does not evaluate treatment effects in trial subjects for a sufficient length of time;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- we may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful, or, if we seek accelerated approval, biomarker efficacy endpoints that applicable regulatory authorities would consider likely to predict clinical benefit;
- preclinical testing may produce results based on which we may decide, or regulators may require us, to conduct additional preclinical studies before we proceed with certain clinical trials, limit the scope of our clinical trials, halt ongoing clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate (for example, we are experiencing difficulty enrolling patients who meet the updated inclusion and exclusion criteria for our trial of pociredir in SCD) or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may decide, or regulators or IRBs may require us, to suspend or terminate clinical trials of our product candidates for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- regulators or IRBs may require us to perform additional or unanticipated clinical trials to obtain approval or we may be subject to additional post-marketing testing requirements to maintain regulatory approval;
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or IRBs to suspend or terminate the trials;
- unforeseen global instability, including political instability, such as the Russian invasion of Ukraine or recent hostilities in Israel and Gaza Strip, or instability from an outbreak of pandemic or contagious disease in or around the countries in which we conduct our clinical trials, could delay the commencement or rate of completion of our clinical trials; and
- regulators may withdraw their approval of a product or impose restrictions on its distribution, such as in the form of a risk evaluation and mitigation strategy, or REMS.

For example, in response to the COVID-19 pandemic, the clinical trial sites for our ReDUX4 trial temporarily postponed trial-related activities, impacting our clinical trial execution plans, and we cannot be certain that we will not face other postponements or similar difficulties in the future. Further, in February 2023, the FDA imposed a clinical hold on our IND for pociredir in SCD, which halted our clinical trial until the FDA lifted the clinical hold in August 2023.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling or a REMS that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

Our product development costs will also increase if we experience delays in testing or in obtaining marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. We may also determine to change the design or protocol of one or more of our clinical trials, including to add additional patients or arms, which could result in increased costs and expenses and/or delays. Significant preclinical study or clinical trial delays also could 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 and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

Because we are developing some of our product candidates for the treatment of diseases in which there is limited clinical experience and, in some cases, using new endpoints or methodologies, the FDA or other regulatory authorities may not consider the endpoints of our clinical trials to predict or provide clinically meaningful results.

There are currently no therapies approved to treat FSHD, and there may be no therapies approved to treat the underlying causes of diseases that we attempt to address or may address in the future. As a result, the design and conduct of a clinical trial or trials of the product candidates for the treatment of these diseases may take longer, be more costly or be less effective as part of the novelty of development in these diseases. In some cases, we may use new or novel endpoints or methodologies, such as RWS, which has not been proven for registration to our knowledge. The FDA and other regulatory authorities have indicated support for RWS as a primary endpoint with additional and appropriate supportive data from secondary endpoints. However, such regulatory authorities may not consider the endpoints of our clinical trial(s) to provide clinically meaningful results, even where we believe such results are clinically meaningful. For example, while we have met with regulators to discuss the REACH trial design and registration strategy for losmapimod for FSHD, including our proposed endpoints for REACH, regulators may require additional data to support the RWS functional primary endpoint for approval of losmapimod for FSHD.

Even if the FDA does find our primary endpoint to be sufficiently validated and clinically meaningful, we may not achieve the pre-specified endpoint to a magnitude, duration or degree of statistical significance in any pivotal or other clinical trials we may conduct for our product candidates. Even if we do meet the primary endpoint, our trials may produce results that are unpredictable or inconsistent with the results of the other, more traditional efficacy endpoints in the trials. The FDA also could ascribe substantial weight to other efficacy endpoints when interpreting the clinical trial data, such that even if we achieve statistically significant results on our primary endpoint, the FDA may regard the failure to show a statistically significant effect on our secondary efficacy endpoints as raising questions about the efficacy of the drug. The FDA also weighs the benefits of a product against its risks and the FDA may view the efficacy results in the context of safety as not being supportive of approval. Other regulatory authorities in Europe and other countries may make similar findings with respect to these endpoints.

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

Identifying and qualifying patients to participate in and complete clinical trials for our product candidates is critical to our success. Successful and timely completion of clinical trials requires that we enroll a sufficient number of patients that meet both the enrollment criteria, and who remain in the trial until its conclusion. For example, in our Phase 1b trial of pociredir, although we enrolled six subjects in the initial cohort, only three subjects remained evaluable as of the initial data cutoff date. Subsequently, we modified the study protocol to monitor subject adherence. However, if such protocols do not improve adherence and improve compliance, we may not be able to generate meaningful data. Furthermore, we may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside of the United States. We revised the design of our clinical trial of pociredir in SCD to address the clinical hold imposed by the FDA, and there can be no certainty as to whether we will be successful in completing the clinical trial with its revised design, which include updated inclusion and exclusion criteria and thus a narrower set of eligible patients, which is making enrollment difficult despite opening a number of sites for such trial. Because of our primary focus on genetically-defined rare diseases, we may have difficulty enrolling a sufficient number of eligible patients.

Patient enrollment is affected by a variety of other factors, including:

- the prevalence and severity of the disease under investigation;
- the eligibility criteria for the trial in question (such as with our trial of pociredir for SCD);
- the perceived risks and benefits of the product candidate under trial;
- the requirements of the trial protocols, including invasive procedures such as muscle biopsies or medical resonance imaging, or MRI, which requires the use of specialized equipment;
- the availability of existing treatments for the indications for which we are conducting clinical trials;
- the ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- the proximity and availability of clinical trial sites for prospective patients;
- the conduct of clinical trials by competitors for product candidates that treat the same indications as our product candidates;
- the ability to identify specific patient populations for biomarker-defined trial cohort(s); and
- the cost to, or lack of adequate compensation for, prospective patients.

Our inability to locate and enroll a sufficient number of patients for our clinical trials would result in significant delays, could require us to abandon one or more clinical trials altogether and could delay or prevent our receipt of necessary regulatory approvals.

Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing.

If serious adverse events or unacceptable side effects are identified during the development of our product candidates, we may need to abandon or limit our development of some of our product candidates.

If our product candidates are associated with serious adverse events or undesirable side effects in clinical trials or have characteristics that are unexpected in clinical trials or preclinical testing, we may need to abandon their development or limit development to more narrow uses or subpopulations in which the serious adverse events, undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective.

For example, in February 2023, the FDA placed our IND for pociredir on clinical hold based on hematological malignancies observed in nonclinical toxicology studies. We addressed the FDA’s concern as diligently as possible, including FDA’s request for information about an SCD patient population with an appropriate benefit-risk profile for further clinical development of pociredir, and FDA's request for information to define the potential risk in any further studies that may be conducted in healthy volunteers. Although the FDA lifted the clinical hold in August 2023, we cannot make assurances that patients treated with pociredir will not develop hematological malignancies or other adverse events in the future. We also cannot make assurances that additional observations in preclinical studies of hematological malignancies or other adverse events will not occur. If such additional adverse events were to

emerge, further advancement of our clinical studies could be halted or delayed and we may not receive regulatory approval for pociredir. Even if we receive regulatory approval for pociredir, our labeling may be restricted and/or market acceptance for our product may be diminished, and the commercial potential of our pociredir program may be materially and negatively impacted.

In pharmaceutical development, many compounds that initially show promise in early-stage or clinical testing are later found to cause side effects that delay or prevent further development of the compound.

Additionally, if results of our clinical trials reveal unacceptable side effects, we, the FDA or the IRBs at the institutions in which our studies are conducted could suspend or terminate our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete any of our clinical trials. If we elect or are forced to suspend or terminate any clinical trial of our product candidates, the commercial prospects of such product candidate will be harmed, and our ability to generate product revenue from such product candidate will be delayed or eliminated. Any of these occurrences could materially harm our business.

If any of our product candidates receives marketing approval and we, or others, later discover that the drug is less effective than previously believed or causes undesirable side effects that were not previously identified, our ability to market the drug could be compromised.

Clinical trials of our product candidates are conducted in carefully defined subsets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. If one or more of our product candidates receives regulatory approval, and we, or others, later discover that they are less effective than previously believed, or cause undesirable side effects, a number of potentially significant negative consequences could result, including:

- withdrawal or limitation by regulatory authorities of approvals of such product;
- seizure of the product by regulatory authorities;
- recall of the product;
- restrictions on the marketing of the product or the manufacturing process for any component thereof;
- requirement by regulatory authorities of additional warnings on the label, such as a “black box” warning or contraindication;
- requirement that we implement a REMS or create a medication guide outlining the risks of such side effects for distribution to patients;
- commitment to expensive post-marketing studies as a prerequisite of approval by regulatory authorities of such product;
- the product may become less competitive;
- initiation of regulatory investigations and government enforcement actions;
- initiation of legal action against us to hold us liable for harm caused to patients; and
- harm to our reputation and resulting harm to physician or patient acceptance of our products.

Any of these events could prevent us from achieving or maintaining market acceptance of a particular product candidate, if approved, and could significantly harm our business, financial condition, and results of operations.

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

Because we have limited financial and managerial resources, we are focusing our research and development efforts on rare neuromuscular, muscular, hematologic and central nervous system disorders. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Failure to allocate resources or capitalize on strategies in a successful manner will have an adverse impact on our business.

We are conducting clinical trials of losmapimod in patients with FSHD in Europe, the United Kingdom, and Canada and currently plan to conduct additional clinical trials for our product candidates at sites outside the United States, and the FDA may not accept data from trials conducted in such locations.

We are currently conducting a Phase 3 clinical trial, an open label extension of our Phase 2b clinical trial, and an open label extension of our Phase 2 open label clinical trial of losmapimod in patients with FSHD in Europe, the United Kingdom, and Canada. We may also conduct additional clinical trials outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of these data is subject to conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and be performed by qualified investigators in accordance with ethical principles. The trial population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will depend on its determination that the trials also complied with all applicable U.S. laws and regulations, including good clinical practices, and FDA's ability to validate the data. If the FDA does not accept the data from any trial that we conduct outside the United States, it would likely result in the need for additional trials, which would be costly and time-consuming and could delay or permanently halt our development of the applicable product candidates.

Risks Related to the Commercialization of our Product Candidates

Even if any of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success, and the market opportunity for any of our product candidates, if approved, may be smaller than we estimate.

If any of our product candidates receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may not be successful. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and potential advantages of our product candidates compared to the advantages and relative risks of alternative treatments;
- the effectiveness of sales and marketing efforts;
- the cost of treatment in relation to alternative treatments, including any similar generic treatments;
- our ability to offer our products, if approved, for sale at competitive prices;
- the clinical indications for which the product is approved;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the timing of market introduction of competitive products;
- the availability of third-party coverage and adequate reimbursement, and patients' willingness to pay out of pocket for required co-payments or in the absence of third-party coverage or adequate reimbursement;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our products, if approved, together with other medications.

Our assessment of the potential market opportunity for our product candidates is based on industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties, one of which we commissioned. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data. Our estimates of the potential market opportunities for our product candidates include several key assumptions based on our industry knowledge, industry publications and third-party research, surveys and studies, which may be based on a small sample size and fail to accurately reflect market opportunities. While we believe that our internal assumptions are reasonable, no independent source has verified such assumptions. If any of our assumptions or estimates, or these publications, research, surveys or studies prove to be inaccurate, then the actual market for any of our product candidates may be smaller than we expect, and as a result our product revenue may be limited and it may be more difficult for us to achieve or maintain profitability.

If we are unable to establish sales, marketing and distribution capabilities or enter into sales, marketing and distribution agreements with third parties, we may not be successful in commercializing our product candidates if and when they are approved.

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any product for which we have obtained marketing approval, we will need to establish a sales, marketing and distribution organization, either ourselves or through collaborations or other arrangements with third parties.

Although we recently entered into the Sanofi Agreement for the potential commercialization of losmapimod outside the United States, we retained rights to our product candidate in the United States. Accordingly, in the future, we expect to build a focused, specialty sales and marketing infrastructure to market some of our product candidates in the United States, if and when they are approved. There are risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force 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 capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. These efforts may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales, marketing, coverage or reimbursement, customer service, medical affairs and other support personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future products;
- the inability of reimbursement professionals to negotiate arrangements for formulary access, reimbursement and other acceptance by payors;
- the inability to price our products at a sufficient price point to ensure an adequate and attractive level of profitability;
- restricted or closed distribution channels that make it difficult to distribute our products to segments of the patient population;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are unable to establish our own sales, marketing and distribution capabilities and we enter into arrangements with third parties to perform these services, our product revenues and our profitability, if any, are likely to be lower than if we were to market, sell and distribute any products that we develop ourselves. In addition, although we reached agreement with Sanofi for losmapimod outside the United States, we may not be successful in entering into additional arrangements with third parties to sell, market and distribute our other product candidates or may be unable to do so on terms that are acceptable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

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

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

For example, we are aware of several product candidates in clinical development that could be competitive with product candidates that we may successfully develop and commercialize. See Item 1 “Business — Competition” in the 2023 Annual Report.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. For example, in December 2023, the FDA approved CASGEVY (exagamglogene autotemcel) and LYFGENIA (lovotibeglogene autotemcel), the first ex vivo cell-based gene therapies for the treatment of SCD. CASGEVY has also been FDA-approved for the treatment of transfusion-dependent beta-thalassemia. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products. If our product candidates achieve marketing approval, we expect that they will be priced at a significant premium over competitive generic products.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

If the market opportunities for our product candidates are smaller than we believe they are, our revenue may be adversely affected, and our business may suffer. Because certain of the target patient populations of our product candidates are small, and the addressable patient population even smaller, we must be able to successfully identify patients and capture a significant market share to achieve profitability and growth.

We primarily focus our research and product development on treatments for genetically-defined rare diseases. Given the small number of patients who have the rare diseases that we are targeting, it is critical to our ability to grow and become profitable that we continue to successfully identify patients with these rare diseases. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, surveys of clinics, patient foundations or market research that we conducted, and may prove to be incorrect or contain errors. New studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. The effort to identify patients with diseases we seek to treat is in early stages, and we cannot accurately predict the number of patients for whom treatment might be possible. Additionally, the potentially addressable patient population for each of our product candidates may be limited or may not be amenable to treatment with our product candidates, and new patients may become increasingly difficult to identify or gain access to, which would adversely affect our results of operations and our business. Further, even if we obtain significant market share for our product candidates, because the potential target populations for many of the indications we are evaluating are very small, we may never achieve profitability despite obtaining such significant market share.

The target patient populations for some of the indications we are evaluating are relatively small, and there is currently no standard of care treatment directed at some of our target indications, such as FSHD. As a result, the pricing and reimbursement of our product candidates, if approved, is uncertain, but must be adequate to support commercial infrastructure. If we are unable to obtain adequate levels of reimbursement, our ability to successfully market and sell our product candidates will be adversely affected.

We rely, and expect to continue to rely, on CMOs to manufacture our product candidates. If we are unable to enter into such arrangements as expected or if such organizations do not meet our supply requirements, development and/or commercialization of our product candidates may be delayed.

We do not have any manufacturing facilities and rely, and expect to continue to rely, on third parties to manufacture clinical supplies of our product candidates and we expect to rely on third parties to manufacture commercial supplies of our products, if and when approved for marketing by applicable regulatory authorities, as well as for packaging, sterilization, storage, distribution and other production logistics. If we are unable to enter into such arrangements on the terms or timeline we expect, development and/or commercialization of our product candidates may be delayed.

If these third parties do not successfully carry out their contractual duties, meet expected deadlines or manufacture our product candidates in accordance with regulatory requirements, if there are disagreements between us and such parties or if such parties are unable to expand capacities to support commercialization of any of our product candidates for which we obtain marketing approval, we may not be able to fulfill, or may be delayed in producing sufficient product candidates to meet, our supply requirements, or 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 manufacturer, which we may not be able to do on reasonable terms, if at all. In either scenario, our clinical trial supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to

manufacture our products or product candidates may be unique or proprietary to the original manufacturer 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 manufacturers for any reason, we will be required to verify that the new manufacturer 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 the FDA or another regulatory authority. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a manufacturer may possess technology related to the manufacture of our product candidate that such manufacturer owns independently. This would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to have another manufacturer manufacture our product candidates. In addition, 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. These facilities may also be affected by natural disasters, such as floods or fire, as well as public health issues (for example, an outbreak of a contagious disease such as COVID-19), or such facilities could face manufacturing issues, such as contamination or regulatory concerns following a regulatory inspection of such facility.

Our third-party manufacturers will be subject to inspection and approval by the FDA before we can commence the manufacture and sale of any of our product candidates, and thereafter subject to FDA inspection from time to time. Failure by our third-party manufacturers to pass such inspections and otherwise satisfactorily complete the FDA approval regimen with respect to our product candidates may result in regulatory actions such as the issuance of FDA Form 483 notices of observations, warning letters or injunctions or the loss of operating licenses.

We or our third-party manufacturers may also encounter shortages in the raw materials or API necessary to produce our product candidates in the quantities needed for our clinical trials or, if our product candidates are approved, in sufficient quantities for commercialization or to meet an increase in demand, as a result of capacity constraints or delays or disruptions in the market for the raw materials or API, including shortages caused by the purchase of such raw materials or API by our competitors or others. The failure of us or our third-party manufacturers to obtain the raw materials or API necessary to manufacture sufficient quantities of our product candidates, may have a material adverse effect on our business.

Our reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

We do not have any manufacturing facilities. Although we believe we have obtained sufficient losmapimod tablets from GSK to complete our ongoing clinical trials of losmapimod for the treatment of FSHD, we cannot be sure we have correctly estimated our drug product and API requirements or that such drug product or API will not expire before we want to use it. We have also engaged CMOs to prepare our own API and to manufacture losmapimod tablets. Although we believe we have produced sufficient losmapimod tablets to complete our Phase 3 registrational trial, we cannot be sure we have correctly estimated our drug product and API requirements or that such drug product or API will not expire before we want to use it, or that we will be able to meet our commitments to supply losmapimod under the Sanofi Agreement. In addition, although we believe we have obtained sufficient quantities of pociredir from a CMO for the completion of our Phase 1b clinical trial for SCD, we cannot be sure we have correctly estimated our drug product requirements, which could delay, prevent or impair our development efforts.

We expect to rely on third parties for the manufacture of pociredir for any future clinical trials and for the manufacture of any future product candidates for preclinical and clinical testing. We also expect to rely on third-party manufacturers or third-party collaborators for the manufacture of commercial supply of any other product candidates for which we or our collaborators obtain marketing approval. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

Our product candidates and any products 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 could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply or a source for bulk drug substance. If any of our future contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers. Although we believe that there are several potential alternative manufacturers who could manufacture our 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 our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

Even if we are able to commercialize any product candidates, the products may become subject to unfavorable pricing regulations, third-party coverage or reimbursement practices or healthcare reform initiatives, which could harm our business.

The regulations that govern marketing approvals, pricing, coverage 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 our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval. See Item 1 “Business — Government Regulation and Product Approval — Pharmaceutical Insurance Coverage and Health Care Reform” in the 2023 Annual Report.

Our ability to commercialize any product candidates 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 government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and 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. Coverage and reimbursement may not be available for any product that we commercialize and, even if these are available, the level of reimbursement may not be satisfactory. Reimbursement may affect the demand for, or the price of, any product candidate for which we obtain marketing approval. Obtaining and maintaining adequate reimbursement for our products may be difficult. We may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. If coverage and adequate 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 we obtain marketing approval. 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.

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 similar regulatory authorities outside of the United States. 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 expenses. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private 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.

There can be no assurance that our product candidates, even if they are approved for sale in the United States or in other countries, will be considered medically reasonable and necessary for a specific indication or cost-effective by third-party payors, or that coverage and an adequate level of reimbursement will be available or that third-party payors’ reimbursement policies will not adversely affect our ability to sell our product candidates profitably.

Our future growth depends, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties that, if they materialize, could harm our business.

Our future profitability will depend, in part, on our ability to commercialize our product candidates in markets outside of the United States and the European Union. If we commercialize our product candidates in foreign markets, we will be subject to additional risks and uncertainties, including:

- economic weakness, including inflation, or political instability in particular economies and markets, which could include localized disputes that have a broader regional or global impact (such as the Russian invasion of Ukraine or recent hostilities in Israel and Gaza Strip);
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements, many of which vary between countries;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- tariffs and trade barriers, as well as other governmental controls and trade restrictions;
- other trade protection measures, import or export licensing requirements or other restrictive actions by U.S. or foreign governments;
- longer accounts receivable collection times;
- longer lead times for shipping;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is common;
- language barriers for technical training;
- reduced protection of intellectual property rights in some foreign countries, and related prevalence of generic alternatives to therapeutics;
- foreign currency exchange rate fluctuations and currency controls;
- differing foreign reimbursement landscapes;
- uncertain and potentially inadequate reimbursement of our products; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

If risks related to any of these uncertainties materializes, it could have a material adverse effect on our business.

Clinical trial and product liability lawsuits against us could divert our resources and could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of clinical trial and product liability exposure related to the testing of our product candidates in human clinical trials, and we will face an even greater risk if we commercially sell any products that we may develop. While we currently have no products that have been approved for commercial sale, the current and future use of product candidates by us in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims might be made by patients that use the product, healthcare providers, pharmaceutical companies or others selling such products. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will 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;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend any related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any products that we may develop.

We currently hold $10 million in clinical trial liability insurance coverage in the aggregate, with a per incident limit of $10 million, which may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. 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. If a successful clinical trial or product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

Risks Related to our Dependence on Third Parties

We rely, and expect to continue to rely, on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, which may harm our business.

We currently rely on third-party contract CROs to conduct our clinical trials. We plan to rely on third-party CROs or third-party research collaboratives to conduct any future clinical trials. We do not plan to independently conduct clinical trials of our other product candidates. We expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct our clinical trials. These agreements might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, our product development activities might be delayed.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities.

If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully develop and commercialize our product candidates. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors.

We also rely, and expect to continue to rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential product revenue.

We have entered into, and may in the future enter into, collaborations with third parties for the discovery, development or commercialization of our product candidates. If our collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates and our business could be adversely affected.

We have a collaboration and license agreement with Sanofi (relating to the commercialization of losmapimod outside of the United States) and with MyoKardia (for certain genetically defined cardiomyopathies). We may in the future enter into additional development, distribution or marketing arrangements with third parties with respect to our other existing or future product candidates. Our likely collaborators for any such sales, marketing, distribution, development, licensing or broader collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. These third party arrangements, including our recent agreement with Sanofi, generally do not provide us with the ability to control the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements.

Collaborations that we enter into, including our collaborations with MyoKardia and Sanofi, may not be successful, and any success will depend heavily on the efforts and activities of such collaborators. Collaborations pose a number of risks, including the following:

- collaborators have significant discretion in determining the amount and timing of efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development of our product candidates or may elect not to continue or renew development programs based on results of clinical trials or other studies, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may not pursue commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew commercialization programs based on results of clinical trials or other studies, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that may divert resources or create competing priorities;

• collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;

• we may not have access to, or may be restricted from disclosing, certain information regarding product candidates being developed or commercialized under a collaboration and, consequently, may have limited ability to inform our stockholders about the status of such product candidates on a discretionary basis;

• collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates and products if the collaborators believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;

• product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;

• a collaborator may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product;

• a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;

• disagreements with collaborators, including disagreements over intellectual property or proprietary rights, contract interpretation or the preferred course of development, might cause delays or terminations of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;

• collaborators may not properly obtain, maintain, enforce, defend or protect our intellectual property or proprietary rights or may use our proprietary information in such a way as to potentially lead to disputes or legal proceedings that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;

• disputes may arise with respect to the ownership of intellectual property developed pursuant to our collaborations;

• collaborators may infringe, misappropriate or otherwise violate the intellectual property or proprietary rights of third parties, which may expose us to litigation and potential liability; and

• collaborations may be terminated for the convenience of the collaborator (e.g., our former collaboration with Acceleron Pharma, Inc.), and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner, or at all. If any collaborations that we enter into do not result in the successful development and commercialization of products or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of our product candidates could be delayed and we may need additional resources to develop our product candidates. All of the risks relating to product development, regulatory approval and commercialization described herein also apply to the activities of our collaborators.

Additionally, subject to its contractual obligations to us, if a collaborator of ours is involved in a business combination, the collaborator might deemphasize or terminate the development or commercialization of any product candidate licensed to it by us. For example, in November 2020, subsequent to our entering into the MyoKardia collaboration agreement, MyoKardia was acquired by Bristol-Myers Squibb Company. Bristol-Myers Squibb Company could determine to reprioritize MyoKardia's development programs such that it ceases to diligently pursue the development of our programs and/or cause the agreement between MyoKardia and us to terminate. If our collaborator terminates its agreement with us, we may find it more difficult to attract new collaborators and our perception in the business and financial communities could be adversely affected.

If we are not able to establish or maintain collaborations, we may have to alter our development and commercialization plans and our business could be adversely affected.

For some of our product candidates, we may decide to collaborate with pharmaceutical or biotechnology companies for the development and potential commercialization of those product candidates. For example, we recently entered into a collaboration and license agreement with Sanofi, granting Sanofi an exclusive license under certain intellectual property rights to commercialize losmapimod outside of the United States. In addition, in July 2020, we entered into a collaboration and license agreement with MyoKardia to identify and validate potential biological targets for the potential treatment of certain genetically defined

cardiomyopathies. We face significant competition in seeking appropriate collaborators, and a number of more established companies may also be pursuing strategies to license or acquire third-party intellectual property rights that we consider attractive. These established companies may have a competitive advantage over us due to their size, financial 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. 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, 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 collaborator 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.

We may also be restricted under existing or future license agreements from entering into agreements on certain terms with potential collaborators. Under our collaboration with MyoKardia, we are restricted from researching, developing, manufacturing, commercializing, using, or otherwise exploiting any compound or product (a) that is a compound or product under the agreement that is directed against certain targets identified by us in the performance of the research activities for the treatment, prophylaxis, or diagnosis of any indication or (b) for the treatment of any genetically defined cardiomyopathies shown to be related to certain specified genes of interest that are modulated by the targets chosen by MyoKardia under our collaboration, in each case, while we are performing the research activities pursuant to the research plan and for a specified period thereafter. Further, our agreement with Sanofi restricts our ability to research, develop, manufacture, commercialize, use, or otherwise exploit any compound or product that binds or otherwise modulates p38a/b MAPK anywhere in the world, except losmapimod in the United States.

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

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms or at all, we may have to curtail the development of a product candidate, 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 fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market.

Risks Related to our Intellectual Property

If we are unable to obtain, maintain, enforce and protect patent protection for our technology and product candidates or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully develop and commercialize our technology and product candidates may be adversely affected.

Our success depends in large part on our ability to obtain and maintain protection of the intellectual property we may own solely and jointly with others or may license from others, particularly patents, in the United States and other countries with respect to any proprietary technology and product candidates we develop. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates that are important to our business and by in-licensing intellectual property related to our technologies and product candidates. If we are unable to obtain or maintain patent protection with respect to any proprietary technology or product candidate, our business, financial condition, results of operations and prospects could be materially harmed.

The patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, defend or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain, enforce and defend the patents, covering technology that we license from third parties. Therefore, these in-licensed patents and applications may not be prepared, filed, prosecuted, maintained, defended and enforced in a manner consistent with the best interests of our business.

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

United States is uncertain and laws of foreign countries may not protect our rights to the same extent as the laws of the United States or vice versa. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. With respect to both owned and in-licensed patent rights, we cannot predict whether the patent applications we and our licensors are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors. Further, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates. In addition, 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 published at all. Therefore, neither we nor our licensors can know with certainty whether either we or our licensors were the first to make the inventions claimed in the patents and patent applications we own or in-license now or in the future, or that either we or our licensors were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our owned and in-licensed patent rights are highly uncertain. Moreover, our owned and in-licensed pending and future patent applications may not result in patents being issued which protect our technology and product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. 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 and our ability to obtain, protect, maintain, defend and enforce our patent rights, narrow the scope of our patent protection and, more generally, could affect the value or narrow the scope of our patent rights. For information relating to our patent portfolio, see Item 1 “Business—Intellectual Property” in the 2023 Annual Report.

Moreover, we or our licensors may be subject to a third-party preissuance submission of prior art to the United States Patent and Trademark Office, or USPTO, or become involved in opposition, derivation, revocation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize drugs without infringing third-party patent rights. If the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. For example, while we believe that the specific and generic claims contained in our U.S. patent provide protection for the method of using losmapimod for the treatment of FSHD and while we also believe that the specific and generic claims contained in our issued and pending U.S. non-provisional and provisional applications provide protection for the pharmaceutical compositions and methods of use for pociredir, third parties may nevertheless challenge such claims. If any such claims are invalidated or rendered unenforceable for any reason, we will lose valuable intellectual property rights and our ability to prevent others from competing with us would be impaired.

Additionally, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if our owned and in-licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and in-licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. Such proceedings also may result in substantial cost and require significant time from our management and employees, even if the eventual outcome is favorable to us. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Furthermore, our competitors may be able to circumvent our owned or in-licensed patents by developing similar or alternative technologies or products in a non-infringing manner. As a result, our owned and in-licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing technology and products similar or identical to any of our technology and product candidates.

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

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. For example, the composition of matter patents covering losmapimod, licensed from GSK have expired and are no longer a barrier to entry for any new uses not covered by our other patents and patent applications.

If we are unable to obtain licenses from third parties on commercially reasonable terms or fail to comply with our obligations under such agreements, our business could be harmed.

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

If we are unable to obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected technology and product candidates, which could harm our business, financial condition, results of operations and prospects significantly.

Additionally, if we fail to comply with our obligations under license agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market, or may be forced to cease developing, manufacturing or marketing, any product that is covered by these agreements or may face other penalties under such agreements. Such an occurrence could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements, or restrictions on our ability to freely assign or sublicense our rights under such agreements when it is in the interest of our business to do so, may result in our having to negotiate new or reinstated agreements with less favorable terms, cause us to lose our rights under these agreements, including our rights to important intellectual property or technology or impede, or delay or prohibit the further development or commercialization of one or more product candidates that rely on such agreements.

Under our current license agreements, we may not have the final or sole decision on whether we are able to opt out certain of our in-licensed European patents and patent applications from the recently created Unified Patent Court, or the UPC, for the European Union. While our licensors have decided to opt out of the UPC, we cannot guarantee that our in-licensed European patents and patent applications will be challenged for non-compliance during the opt-out procedure and if successful, brought under the jurisdiction of the UPC, nor can we guarantee that our licensors will decide to opt back into the UPC at a later time. Thus, we cannot be certain that our in-licensed European patents and patent applications will not fall under the jurisdiction of the UPC. Under the UPC, a single European patent would be valid and enforceable in numerous European countries. A challenge to the validity of a European patent under the UPC, if successful, could result in a loss of patent protection in numerous European countries which could have a material adverse impact on our business and our ability to commercialize or license our technology and product candidates.

If we do not obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, our business may be materially harmed.

In the United States, the patent term of a patent that covers an FDA-approved drug may be eligible for limited patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to, among other factors, the length of time the drug is under regulatory review, but such patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only one eligible patent may be extended. Similar provisions are available in Europe and certain other jurisdictions outside the United States. If and when our product candidates receive FDA approval, we expect to apply for patent term extensions where applicable, but there is no guarantee that the applicable governmental authorities will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions. We may not be granted patent term extension either in the United States or in any foreign country because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. If we are unable to obtain any patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following the expiration of our patent rights, and our business, financial condition, results of operations and prospects could be materially harmed.

Further, for our licensed patents, we may not have the right to control prosecution, including filing with the USPTO a petition for patent term extension thus if one of our licensed patents is eligible for patent term extension, we may not be able to control whether a petition to obtain a patent term extension is filed, or obtained, from the USPTO.

There are detailed rules and requirements regarding the patents that may be submitted to the FDA for listing in the Orange Book. We may be unable to obtain patents covering our product candidates that contain one or more claims that satisfy the requirements for listing in the Orange Book. Even if we submit a patent for listing in the Orange Book, the FDA may decline to list the patent, or a manufacturer of generic drugs may challenge the listing. If one of our product candidates is approved and a patent covering that product candidate is not listed in the Orange Book, an ANDA applicant would not have to provide notice to us with respect to that patent. See Item 1 “Business—Intellectual Property” in the 2023 Annual Report for additional information regarding patent laws and patent protection.

Our issued European patents could be subject to the jurisdiction of the UPC.

Our European patents and patent applications could be challenged in the UPC. We decided to remove, i.e., opt out, our European patents and patent applications from the jurisdiction of the UPC. However, if certain formalities and requirements are not met, our European patents and patent applications could be challenged for non-compliance and brought under the jurisdiction of the UPC. We cannot be certain that our European patents and patent applications will avoid falling under the jurisdiction of the UPC. Under the UPC, a granted European patent would be valid and enforceable in numerous European countries. Although such patent rights would apply to numerous European countries, a successful challenge to a European patent under the UPC could result in loss of patent protection in numerous European countries. Accordingly, a single proceeding under the UPC addressing the validity and infringement of the European patent could result in loss of patent protection in numerous European countries rather than in each validated country separately as such patents always have been adjudicated. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and product candidates.

Changes to patent laws in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

Changes in either the patent laws or interpretation of patent laws in the United States, including patent reform legislation such as the Leahy-Smith America Invents Act, or the Leahy-Smith Act, could increase the uncertainties and costs surrounding the prosecution of our owned and in-licensed patent applications and the maintenance, enforcement or defense of our owned and in-licensed issued patents. The Leahy-Smith Act includes a number of significant changes to United States patent law. These changes include provisions that affect the way patent applications are prosecuted, redefine prior art, provide more efficient and cost-effective avenues for competitors to challenge the validity of patents, and enable third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent at USPTO-administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith Act, the United States transitioned to a first-to-file system in which, assuming that the other statutory requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. As such, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our patent rights and our ability to protect, defend and enforce our patent rights in the future.

Although we or our licensors are not currently involved in any litigation to protect or enforce our patent or other intellectual property rights, we may become involved in such lawsuits, which could be expensive, time-consuming and unsuccessful.

Competitors and other third parties may infringe, misappropriate or otherwise violate our or our licensor's issued patents or other intellectual property. As a result, we or our licensors may need to file infringement, misappropriation or other intellectual property related claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke such parties to assert counterclaims against us alleging that we infringe, misappropriate or otherwise violate their intellectual property. In addition, in a patent infringement proceeding, such parties could counterclaim that the patents we or our licensors have asserted are 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. Third parties may institute such claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, *inter partes* review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (*e.g.*, opposition proceedings). The outcome following legal assertions of invalidity and unenforceability is unpredictable.

An adverse result in any such proceeding could put one or more of our owned or in-licensed patents at risk of being invalidated or interpreted narrowly, and could put any of our owned or in-licensed patent applications at risk of not yielding an issued patent. A court may also refuse to stop the third party from using the technology at issue in a proceeding on the grounds that our owned or in-licensed patents do not cover such technology. 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 or trade secrets could be compromised by disclosure during this type of litigation. Any of the foregoing could allow such third parties to develop and commercialize competing technologies and products and have a material adverse impact on our business, financial condition, results of operations and prospects.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. Our defense of litigation or interference or derivation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with 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 development partnerships that would help us bring our product candidates to market.

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. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties. There is considerable patent and other intellectual property litigation in the pharmaceutical and biotechnology industries. We may become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our technology and product candidates, including interference proceedings, post grant review, *inter partes* review, and derivation proceedings before the USPTO and similar proceedings in foreign jurisdictions such as oppositions before the European Patent Office. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our technologies or product candidates that we may identify may be subject to claims of infringement of the patent rights of third parties.

The legal threshold for initiating litigation or contested proceedings is low, so that even lawsuits or proceedings with a low probability of success might be initiated and require significant resources to defend. Litigation and contested proceedings can also be expensive and time-consuming, and our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. The risks of being involved in such litigation and proceedings may increase if and as our product candidates near commercialization and as we gain the greater visibility associated with being a public company. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of merit. We may not be aware of all such intellectual property rights potentially relating to our technology and product candidates and their uses, or we may incorrectly conclude that third party intellectual property is invalid or that our activities and

product candidates do not infringe such intellectual property. Thus, we do not know with certainty that our technology and product candidates, or our development and commercialization thereof, do not and will not infringe, misappropriate or otherwise violate any third party's intellectual property.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations or methods, such as methods of manufacture or methods for treatment, related to the discovery, use or manufacture of the product candidates that we may identify or related to our technologies. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that the product candidates that we may identify may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Moreover, as noted above, there may be existing patents that we are not aware of or that we have incorrectly concluded are invalid or not infringed by our activities. If any third-party patents were held by a court of competent jurisdiction to cover, for example, the manufacturing process of the product candidates that we may identify, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize the product candidates that we may identify. 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. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

We may choose to take a license or, if we are found to infringe, misappropriate or otherwise violate a third party's intellectual property rights, we could also be required to obtain a license from such third party to continue developing, manufacturing and marketing our technology and product candidates. However, we may not be able to obtain any required license 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 could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technology or product. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right and could be forced to indemnify our customers or collaborators. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. In addition, we may be forced to redesign our product candidates, seek new regulatory approvals and indemnify third parties pursuant to contractual agreements. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar material adverse effect on our business, financial condition, results of operations and prospects.

Intellectual property litigation or other legal proceedings relating to intellectual property could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

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

Obtaining and maintaining 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, renewal and annuity fees and various other government fees on any issued patent and pending patent application must be paid to the USPTO and foreign patent agencies in several stages or annually over the lifetime of our owned and in-licensed 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 process. In certain circumstances, we rely on our licensing partners to pay these fees to, or comply with the procedural and documentary rules of, the relevant patent agency. With respect to our patents, we rely on an annuity service, outside firms and outside counsel to remind us of the due dates and to make payment after we instruct them to do so. While an inadvertent lapse can in many 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. In such an event, potential competitors might be able to enter the market with similar or identical products or technology. If we or our licensors fail to maintain the patents and patent applications covering our product candidates, it would have a material adverse effect on our business, financial condition, results of operations and prospects.

If we fail to comply with our obligations in our intellectual property licenses and funding arrangements with third parties, or otherwise experience disruptions to our business relationships with our licensors, we could lose intellectual property rights that are important to our business.

We are party to license and funding agreements, such as our agreement with GSK and our license agreement with CAMP4, and we may enter into additional licensing and funding arrangements with third parties that impose or may impose diligence, development and commercialization timelines, milestone payment, royalty, insurance and other obligations on us. Under our existing licensing and funding agreements, we are obligated to pay royalties on net product sales of product candidates or related technologies to the extent they are covered by the agreements. If we fail to comply with such obligations under current or future license and funding agreements, our counterparties may have the right to terminate these agreements or require us to grant them certain rights. Such an occurrence could materially adversely affect the value of any product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology, which would have a material adverse effect on our business, financial condition, results of operations and prospects. We also have licenses and agreements to certain technologies that we use in our discovery efforts, all of which are non-exclusive. While we still face all of the risks described herein with respect to those agreements, we cannot prevent third parties from also accessing those technologies. In addition, our licenses may place restrictions on our future business opportunities.

Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

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

Our current or future licensors may have relied on third-party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents and patent applications we in-license. If other third parties have ownership rights to patents or patent applications we in-license, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

In spite of our best efforts, our licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize product candidates and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying intellectual property fails to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products and technologies identical to ours. This could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

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

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States, and even where such protection is nominally available, judicial and governmental enforcement of such intellectual property rights may be lacking. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection or licenses but enforcement is not as strong as that in the United States. These products may compete with our products, and our 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 and in Russia, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. In addition, certain jurisdictions do not protect to the same extent or at all inventions that constitute new methods of treatment.

Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

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

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets or other intellectual property as an inventor or co-inventor. For example, we or our licensors may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or our or our licensors' ownership of our owned or in-licensed patents, trade secrets or other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may be subject to claims by third parties asserting that our employees, consultants or contractors have wrongfully used or disclosed confidential information of third parties, or we have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees, consultants and contractors were previously employed at universities or other pharmaceutical or biotechnology companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims.

In addition, while it is our policy to require our employees, consultants and contractors who may be involved in the 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 develops intellectual property that we regard as our own. Our intellectual property assignment agreements with them may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims 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 conditions, results of operations and prospects.

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, which could have a material adverse effect on our competitive business position and prospects. 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, which license may not be available on commercially reasonable terms, or at all, or such license may be non-exclusive. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and employees.

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

In addition to seeking patents for our product candidates, we also rely on trade secrets and confidentiality agreements to protect our unpatented know-how, technology and other proprietary information, to maintain our competitive position, including certain aspects of our discovery technology. We seek to protect our trade secrets and other proprietary technology, 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, CROs, CMOs, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants, but we cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Detecting the disclosure or misappropriation of a trade secret and enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside of the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed.

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 product candidates that are similar to ours but that are not covered by the claims of the patents that we own;
- we, or our license partners or current or future collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent applications that we license or may own in the future;
- we, or our license partners or 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 in-licensed intellectual property rights;

• it is possible that our owned and in-licensed pending patent applications or those we may own or in-license 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 cannot ensure that any of our patents, or any of our pending patent applications, if issued, or those of our licensors, will include claims having a scope sufficient to protect our product candidates;

• we cannot ensure that any patents issued to us or our licensors will provide a basis for an exclusive market for our commercially viable product candidates or will provide us with any competitive advantages;

• we cannot ensure that our commercial activities or product candidates will not infringe upon the patents of others;

• we cannot ensure that we will be able to successfully commercialize our product candidates on a substantial scale, if approved, before the relevant patents that we own or license expire;

• portions of our discovery technology are protected by trade secrets, but much is not protected by intellectual property, including patents, trade secrets and know-how, and we may not be able to develop, acquire or in-license any patentable technologies or other intellectual property related to the unprotected portions of our discovery portfolio;

• 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 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.

Risks Related to Regulatory Approval of our Product Candidates and Other Legal Compliance Matters

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain, and we may not obtain approvals for the commercialization of some or all of our product candidates. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired.

Marketing approval of drugs in the United States requires the submission of a new drug application, or NDA, to the FDA and we are not permitted to market any drug candidate in the United States until we obtain approval of the NDA. An NDA must be supported by extensive clinical and preclinical data, as well as extensive information regarding pharmacology, chemistry, manufacturing and controls. We have not submitted an application for or received marketing approval for any of our product candidates in the United States or in any other jurisdiction.

We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party clinical research organizations or other third-party consultants or vendors to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information, including manufacturing information, to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. If any of our product candidates receives marketing approval, the accompanying label may limit the approved use of our drug, which could limit sales of the product.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

Disruptions at the FDA and other agencies may prolong the time necessary for regulatory submissions to be reviewed and/or new drugs to be approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown were to occur, 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.

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

We may not be able to obtain or maintain orphan drug designation or exclusivity for our product candidates and, even if we do, that exclusivity may not prevent the FDA or the EMA from approving other competing products.

Regulatory authorities in some jurisdictions, including the United States and European Union, may designate drugs for relatively small patient populations as orphan drugs. The FDA and EMA have granted orphan drug designation to losmapimod for the treatment of FSHD. We may seek orphan drug designation for our other current and future product candidates.

Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of market exclusivity, which precludes the FDA or the EMA from approving another marketing authorization application for the same drug for a certain time period. The applicable period is seven years in the United States and ten years in the European Union. The exclusivity period in the European Union can be reduced to six years at the end of the fifth year if it is determined that a product no longer meets the criteria for orphan designation, including if the product is sufficiently profitable so that market exclusivity is no longer justified. Proposed amendments to European Union regulations regarding orphan medicines are under consideration which, if approved, could reduce the ten-year marketing exclusivity period.

Orphan drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because competing drugs containing a different active ingredient can be approved for the same condition. In addition, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior to the first drug to obtain orphan drug exclusivity because it is shown to be safer, more effective or makes a major contribution to patient care. Moreover, if we pursue and obtain approval for the same product for another indication for which we are not entitled to or do not have orphan drug exclusivity, our period of orphan exclusivity will not prevent third parties from obtaining approval for a competing drug containing the same active ingredient for use in this other, non-orphan indication. If that were to occur, the protection we derive from orphan exclusivity may be adversely affected.

Designation by the FDA, such as fast track or breakthrough therapy, may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval.

The FDA granted fast track designation to losmapimod for the treatment of FSHD and to pociredir for the treatment of SCD, and we may seek fast track designation for some of our other product candidates as well as breakthrough therapy designation, including for losmapimod. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA 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, we cannot assure stockholders that the FDA would decide to grant it. Even with fast track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial

improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development.

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. Even if we receive breakthrough therapy designation, the receipt of such designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the products no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Even if the FDA agrees that we may pursue an accelerated approval NDA submission, approval of the NDA is not assured, nor does submission of an accelerated approval NDA ensure that the product candidate will have a faster development or regulatory review process.

We may seek approval, as applicable, of our product candidates using the FDA's accelerated approval pathway. A product may be eligible for accelerated approval if it treats a serious 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 or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, or IMM, that is reasonably likely to predict an effect on IMM or other clinical benefit (*i.e.*, an intermediate clinical endpoint).

Prior to seeking such accelerated approval, we will seek feedback from the FDA and otherwise evaluate our ability to seek and receive such accelerated approval.

There can be no assurance that, after feedback from FDA, we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval or under another expedited regulatory designation, there can be no assurance that such submission or application will be accepted or that any expedited review or approval will be granted on a timely basis, or at all.

Moreover, as a condition of accelerated approval, the FDA likely would require that we perform adequate and well-controlled post-marketing clinical trials to confirm the product's clinical benefit. These confirmatory trials must be completed with due diligence. Under the Food and Drug Omnibus Reform Act of 2022, or FDORA, the FDA is permitted to require, as appropriate, that a post-approval confirmatory study or studies be underway prior to approval or within a specified time period after the date of approval for a product granted accelerated approval. FDORA also requires sponsors to send updates to the FDA every 180 days on the status of such studies, including progress toward enrollment targets, and the FDA must promptly post this information publicly. FDORA also gives the FDA increased authority to withdraw approval of a drug or biologic granted accelerated approval on an expedited basis if the sponsor fails to conduct such studies in a timely manner, send the necessary updates to the FDA, or if such post-approval studies fail to verify the drug's predicted clinical benefit. Under FDORA, the FDA is empowered to take action, such as issuing fines, against companies that fail to conduct with due diligence any post-approval confirmatory study or submit timely reports to the agency on their progress. In addition, the FDA generally requires pre-approval of promotional materials for products under consideration for accelerated approval, which could adversely impact the timing of the commercial launch of the product. Thus, even if we seek to utilize the accelerated approval pathway for a product candidate, we may not experience a faster development or regulatory review or approval process for that product. In addition, receiving accelerated approval does not assure that the product's accelerated approval will ultimately be converted to a traditional approval.

Failure to obtain marketing approval in foreign jurisdictions would prevent our product candidates from being marketed abroad.

In order to market and sell our products in the European Union and many other foreign jurisdictions, we or our potential third-party collaborators 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 of the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside of the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We or our potential third-party collaborators may not obtain approvals, including conditional authorization, from regulatory authorities outside of the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside of the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in other countries. We may not be able to file for marketing approvals and may not receive the necessary approvals to commercialize our products in any market.

Additionally, now that the United Kingdom is no longer part of the European Union, separate applications and procedures will be required to obtain regulatory approval for our products in the United Kingdom and the European Union. Any delay in obtaining, or an inability to obtain, any marketing approvals could prevent us from commercializing any product candidates in the United Kingdom and/or the European Union and restrict our ability to generate revenue and achieve and sustain profitability.

Any product candidate for which we obtain marketing approval could be subject to post-marketing restrictions or withdrawal from the market and we may be subject to substantial penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved.

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, including the requirement to implement a REMS. If any of our product candidates receives marketing approval, the accompanying label may limit the approved use of our drug, which could limit sales of the product.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product, including the adoption and implementation of REMS. The FDA and other agencies, including the Department of Justice, or the DOJ, closely regulate and monitor the post-approval marketing and promotion of drugs to ensure they are marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. Violations of the FDCA and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription drugs may lead to investigations and enforcement actions alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may have various consequences, including:

- suspension of or restrictions on such products, manufacturers or manufacturing processes;
- restrictions and warnings on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension of any ongoing clinical trials;
- suspension or withdrawal of marketing approvals;
- damage to relationships with any potential collaborators;

- unfavorable press coverage and damage to our reputation;
- refusal to permit the import or export of our products;
- product seizure or detention;
- injunctions or the imposition of civil or criminal penalties; or
- litigation involving patients using our products.

Non-compliance with European Union requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with the European Union's or United Kingdom's requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to cGMPs applicable to drug manufacturers. Additionally, under FDORA, sponsors of approved drugs and biologics must provide six months' notice to the FDA of any changes in marketing status, such as the withdrawal of a drug, and failure to do so could result in the FDA placing the product on a list of discontinued products, which would revoke the product's ability to be marketed. We will also be subject to other regulatory requirements, including submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements regarding the distribution of samples to clinicians, and recordkeeping.

Our relationships with healthcare providers, physicians and third-party payors will be subject to applicable anti-kickback, fraud and abuse, false claims, transparency, health information privacy and security, and other healthcare laws and regulations, which, in the event of a violation, could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

If we obtain regulatory approval and commercialize any products, 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 future arrangements with healthcare providers, physicians and third-party payors may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any products for which we obtain marketing approval. In addition, we may be subject to transparency laws and patient privacy regulation by U.S. federal and state governments and by governments in foreign jurisdictions in which we conduct our business. See Item 1 "Business—Government Regulation and Product Approvals—Health Care Law and Regulation" in the 2023 Annual Report.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Efforts to ensure that our business arrangements with third parties will 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 involving applicable fraud and abuse or other healthcare laws and regulations. If our operations, including anticipated activities that would be conducted by our sales team, 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, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government funded healthcare programs.

Compliance with global privacy and data security requirements could result in additional costs and liabilities to us or inhibit our ability to collect and process data globally, and the failure to comply with such requirements could subject us to significant fines and penalties, which may have a material adverse effect on our business, financial condition or results of operations.

The legislative and regulatory framework for the collection, use, safeguarding, sharing, transfer and other processing of information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Globally, virtually every jurisdiction in which we operate has established its own data security and privacy frameworks with which we must comply. For example, the collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the European Economic Area, or EEA, including personal health data, is subject to the European Union's General Data Protection Regulation, or EU GDPR. Following the withdrawal of the United Kingdom from the European Union, or Brexit, the EU GDPR has been incorporated into

United Kingdom's laws, or UK GDPR, alongside the UK Data Protection Act 2018, and together with the EU GDPR, is referred to as GDPR.

Despite Brexit, the EU and UK GDPR remain largely aligned. Currently, the most impactful point of divergence relates to transfer mechanisms (i.e., the ability for companies in the European Union or the United Kingdom to transfer personal information to third countries, including the United States), because it requires us to implement a variety of different contractual clauses approved by European Union's or United Kingdom's regulators, and carry out transfer impact assessments to establish whether the third country can ensure essential equivalency. This complexity and the additional contractual burden increases our overall risk exposure, and may result in us needing to make strategic considerations around where EEA and UK personal data is stored and which service providers we can utilize for the processing of EEA and UK personal data.

There may be further divergence in the future, including with regard to administrative burdens. The UK Government has also now introduced a Data Protection and Digital Information Bill, or the UK Bill, into the UK legislative process. The aim of the UK Bill is to reform the UK's data protection regime following Brexit. If passed, the final version of the UK Bill may have the effect of further altering the similarities between the UK and EEA data protection regime. This may lead to additional compliance costs and could increase our overall risk exposure as we may no longer be able to take a unified approach across the European Union and the United Kingdom, and we will need to amend our processes and procedures to align with the new framework.

Similar data protection laws are either in place or under way in the United States. There are a broad variety of privacy and data security laws and regulations that may be applicable to our activities governing the collection, use, disclosure, and protection of health-related and other personal information (including, state data breach notification laws, health information and/or genetic privacy laws and federal and state consumer protection laws including Section 5 of the FTC Act, HIPAA, and the California Consumer Privacy Act, or CCPA). For example, the CCPA as amended by the California Privacy Rights Act, has created certain requirements for data use, sharing and transparency, and provides California residents certain rights concerning their personal information, such as access, correction, deletion and opt out of selling or sharing such data. Several other states have implemented privacy legislation similar to the CCPA or are preparing to implement their own regulatory frameworks. For example, Washington state's My Health My Data Act, which took effect in March 2024, expands the definition of consumer health data, affords consumers with privacy rights and creates a private right of action, which could generate litigation. A wide range of enforcement agencies at both the state and federal levels, such as the Federal Trade Commission and state Attorneys General have been increasingly aggressive in reviewing and enforcing privacy and data security-related consumer protection laws. See Item 1 "Business –Government Regulation and Product Approvals" in the 2023 Annual Report.

Given the breadth and depth of changes in privacy, data protection and consumer protection obligations, preparing for and complying with these requirements is rigorous and time intensive and requires significant resources and ongoing review of our technologies, systems and practices, as well as those of any third-party collaborators, service providers, contractors or consultants that store, process or transfer personal data on our behalf. Compliance with the GDPR and other similar laws or regulations associated with the enhanced protection of certain types of sensitive data, such as healthcare data or other personal information from our clinical trials, could require us to change our business practices and put in place additional compliance mechanisms, may interrupt or delay our development, regulatory and commercialization activities and increase our cost of doing business. Any failure or perceived failure by us to comply with such laws and regulations could lead to government enforcement actions, private litigation and significant fines and penalties against us and could have a material adverse effect on our business, financial condition or results of operations. There is also the threat of consumer class actions related to these laws and the overall protection of personal data. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our reputation and our business.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain for any products that are approved in the United States or foreign jurisdictions.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. The pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by legislative initiatives. Current laws, as well as other healthcare reform measures that 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 FDA approved product. If reimbursement of our products is unavailable or limited in scope, our business could be materially harmed. See Item 1 "Business—Government Regulation and Product Approval—Pharmaceutical Insurance Coverage and Health Care Reform" in the 2023 Annual Report.

In August 2022 the Inflation Reduction Act of 2022 was passed, which among other things, allows for Centers for Medicare & Medicaid Services to negotiate prices for certain single-source drugs and biologics reimbursed under Medicare Part B and Part D, beginning with select high-cost drugs in 2026. The legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for offering a price that is not equal to or less than the price negotiated under the law or for taking price increases that

exceed inflation. The legislation also requires manufacturers to pay rebates for drugs in Medicare Part D whose price increases exceed inflation. Further, the legislation caps Medicare beneficiaries' annual out-of-pocket drug expenses at $2,000. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA's Medicare drug price negotiation program. The effect of Inflation Reduction Act of 2022 on our business and the healthcare industry in general is not yet known.

The continuing efforts of the government, insurance companies, managed care organizations and other payers of healthcare services to contain or reduce costs of healthcare may adversely affect:

- the demand for any of our product candidates, if approved;
- the ability to set a price that we believe is fair for any of our product candidates, if approved;
- our ability to generate revenues and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

We expect that these healthcare reforms, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product and/or the level of reimbursement physicians receive for administering any approved product we might bring to market. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which our products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

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

In countries outside of the United States, 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 product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

If we or any third-party manufacturers we engage now or in the future fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs or liabilities that could harm our business.

We and third-party manufacturers we engage now are, and any third-party manufacturers we may engage in the future will be, subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. Liability under certain environmental laws governing the release and cleanup of hazardous materials is joint and several and could be imposed without regard to fault. We also could incur significant costs associated with civil or criminal fines and penalties or become subject to injunctions limiting or prohibiting our activities for failure to comply with such laws and regulations.

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

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Further, with respect to the operations of our current and any future third-party contract manufacturers, it is possible that if they fail to operate in compliance with applicable environmental, health and safety laws and regulations or properly dispose of wastes associated with our products, we could be held liable for any resulting damages, suffer reputational harm or experience a disruption in the manufacture and supply of our product candidates or products. In addition, our supply chain may be adversely impacted if any of our third-party contract manufacturers become subject to injunctions or other sanctions as a result of their non-compliance with environmental, health and safety laws and regulations.

We are subject to anti-corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures and legal expenses, be precluded from developing manufacturing and selling certain products outside the United States or be required to develop and implement costly compliance programs, which could adversely affect our business, results of operations and financial condition.

Our operations are subject to anti-corruption laws, including the U.K. Bribery Act 2010, or Bribery Act, the U.S. Foreign Corrupt Practices Act, or FCPA, and other anti-corruption laws that apply in countries where we do business and may do business in the future. The Bribery Act, FCPA and these other laws generally prohibit us, our officers, and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. Compliance with the FCPA, in particular, is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

We may in the future operate in jurisdictions that pose a high risk of potential Bribery Act or FCPA violations, and we may participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the Bribery Act, FCPA or local anti-corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted. If we expand our operations outside of the United States, we will need to dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United Kingdom and the United States, and authorities in the European Union, including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations, collectively referred to as the Trade Control laws. In addition, various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the Bribery Act, the FCPA or other legal requirements, including Trade Control laws. If we are not in compliance with the Bribery Act, the FCPA and other anti-corruption laws or Trade Control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions. Any investigation of any potential violations of the Bribery Act, the FCPA, other anti-corruption laws or Trade Control laws by United Kingdom, United States or other authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition.

Our employees, independent contractors, consultants and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading, which could cause significant liability for us and harm our reputation.

We are exposed to the risk of fraud or other misconduct by our employees, independent contractors, consultants and vendors. Misconduct by these partners could include intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. This could include violations of HIPAA, other U.S. federal and state law, and requirements of non-U.S. jurisdictions, including the EU GDPR. We are also exposed to risks in connection with any insider trading violations by employees or others affiliated with us. 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 governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws, standards, regulations, guidance or codes of conduct. 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 and results of operations, including the imposition of significant fines or other sanctions.

Our internal computer and information technology systems and infrastructure, or those of our collaborators or other contractors or consultants, may fail or suffer security compromises or breaches, which could result in a material disruption of our product development programs.

Our internal computer and information technology systems and infrastructure and those of our CROs, collaborators, and other contractors or consultants upon which our business relies, are vulnerable to breakdown or damage or interruption or otherwise may sustain damage from computer viruses, unauthorized access, data breaches, phishing attacks, cybercriminals, system malfunction, natural disasters (including hurricanes and earthquakes), terrorism, war and telecommunication and electrical failures. Such systems and infrastructure are also vulnerable to service interruptions or to security compromises or breaches from inadvertent or intentional actions by our employees, CROs or other third-party vendors, contractors, consultants and/or business partners or other third parties, or from cyber-attacks by malicious third parties. Cyber-attacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyber-attacks could include wrongful conduct by insider employees or vendors, hostile foreign governments, industrial espionage, wire fraud and other forms of cyber fraud or cyber-attacks, including the deployment of harmful malware, ransomware, denial-of-service attacks, unauthorized access to or deletion of files, phishing attacks and social engineering, business email compromise, and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. We have experienced cyber incidents in the past, and we cannot guarantee that the measure we take to prevent, detect and respond to cyber-attacks will be effective to prevent or remediate future incidents. If our cybersecurity measures or those of our service providers fail to protect against unauthorized access, attacks, compromise or the mishandling of data by our employees or contractors, then our reputation, customer trust, business, results of operations and financial condition could be adversely affected. Because the techniques used by threat actors who may attempt to penetrate and sabotage our computer systems or those of our collaborators or other contractors or consultants change frequently and may not be recognized until launched against a target, we may be unable to anticipate these techniques.

While we have not experienced any material system failure, accident, cyber-attack 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, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security compromise or breach were to result in a loss of, damage to, unauthorized access, or misuse of our data, systems, infrastructure or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability (including in connection with or resulting from litigation or governmental investigations and enforcement actions), our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed and our business could be otherwise adversely affected.

Risks Related to Employee Matters and Managing Growth

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

We are highly dependent on the research and development, clinical, financial, operational and other business expertise of our executive officers, as well as the other principal members of our management, scientific and clinical teams. Although we have entered into employment offer letters with our executive officers, each of them may terminate their employment with us at any time. We do not maintain “key person” insurance for any of our executives or other employees. Recruiting and retaining qualified scientific, clinical, manufacturing, accounting, legal and sales and marketing personnel will also be critical to our success.

We have had recent executive transitions, including of our chief executive officer, chief financial officer, president of research and development, chief scientific officer, and chief medical officer. We cannot predict the likelihood, timing or effect of future transitions among our executive leadership. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. Even if we are successful in our efforts to replace our executive leadership, we cannot guarantee that we will not face similar turnover in the future. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. In August 2022, we announced a workforce reduction in our research and development function, which may make us a less attractive employer to future candidates. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. Our success as a public company also depends on implementing and maintaining internal controls and the accuracy and timeliness of our financial reporting. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

We expect to expand our development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, clinical, regulatory affairs and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Risks Related to our Common Stock

Our executive officers, directors and principal stockholders, if they choose to act together, have the ability to control or significantly influence all matters submitted to stockholders for approval.

As of July 24, 2024, our executive officers and directors and our stockholders who owned more than 5% of our outstanding common stock in the aggregate beneficially owned shares representing approximately 47.4% of our capital stock. As a result, if these stockholders were to choose to act together, they would be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets.

This concentration of ownership control may:

- delay, defer or prevent a change in control;
- entrench our management and board of directors; or
- delay or prevent a merger, consolidation, takeover or other business combination involving us that other stockholders may desire.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current directors and members of management.

Provisions in our certificate of incorporation and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that only one of three classes of directors is elected each year;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from our board of directors;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a “poison pill” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal specified provisions of our certificate of incorporation or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or the DGCL, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

If securities analysts do not publish or cease publishing research or reports or publish misleading, inaccurate or unfavorable research about our business or if they publish negative evaluations of our stock, the price and trading volume of our stock could decline.

The trading market for our common stock relies, in part, on the research and reports that industry or financial analysts publish about us or our business. There can be no assurance that existing analysts will continue to cover us or that new analysts will begin to cover us. There is also no assurance that any covering analyst will provide favorable coverage. Although we have obtained analyst coverage, if one or more of the analysts covering our business downgrade their evaluations of our stock or publish inaccurate or unfavorable research about our business, or provides more favorable relative recommendations about our competitors, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price and trading volume to decline.

The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for our stockholders.

The trading price of our common stock has been, and is likely to continue to be volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. The stock market in general and the market for smaller biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price for our common stock may be influenced by many factors, including:

- results of or developments in preclinical studies and clinical trials of our product candidates or those of our competitors or potential collaborators;
- our success in commercializing our product candidates, if and when approved;
- the success of competitive products or technologies;

- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other intellectual property or proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license products, product candidates, technologies or data referencing rights, the costs of commercializing any such products and the costs of development of any such product candidates or technologies;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or the financial results of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this “Risk Factors” section.

In the past, following periods of volatility in the market price of a company’s securities, securities class-action litigation has often been instituted against that company. Any lawsuit to which we are a party, with or without merit, may result in an unfavorable judgment. We also may decide to settle lawsuits on unfavorable terms. Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our offerings or business practices. Such litigation may also cause us to incur other substantial costs to defend such claims and divert management’s attention and resources. Furthermore, negative public announcements of the results of hearings, motions or other interim proceedings or developments could have a negative effect on the market price of our common stock.

A significant portion of our total outstanding shares are eligible to be sold into the market, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Persons who were our stockholders prior to our initial public offering continue to hold a substantial number of shares of our common stock. If such persons sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline.

In addition, we have filed or intend to file universal shelf registration statements (which allows us to offer and sell securities from time to time pursuant to one or more offerings at prices and terms to be determined at the time of sale) subject to an aggregate offering amount stated therein, as well as registration statements registering all shares of common stock that we may issue under our equity compensation plans or pursuant to equity awards made to newly hired employees outside of equity compensation plans. Such registered shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates.

We are an “emerging growth company,” and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an “emerging growth company,” or EGC, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. We may remain an EGC until December 31, 2024, although if the market value of our common stock that is held by non-affiliates exceeds $700 million as of any June 30 before that time or if we have annual gross revenues of $1.235 billion or more in any fiscal year, we would cease to be an EGC as of December 31 of the applicable year. We also would cease to be an EGC if we issue more than $1 billion of non-convertible debt over a three-year period. For so long as we remain an EGC, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not EGCs. These exemptions include:

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply 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;

• reduced disclosure obligations regarding executive compensation; and

• exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

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

In addition, the JOBS Act permits an EGC to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected not to "opt out" of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that we either (i) irrevocably elect to "opt out" of such extended transition period or (ii) no longer qualify as an EGC.

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

As a public company we have incurred, and particularly after we are no longer an EGC, we will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Global Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs, particularly as we hire additional financial and accounting employees to meet public company internal control and financial reporting requirements, and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified members of our board of directors.

We are evaluating these rules and regulations, and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we are required to furnish a report by our management on our internal control over financial reporting. However, while we remain an EGC or a smaller reporting company with less than $100 million in revenue, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we conduct a process each year to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, including through hiring additional financial and accounting personnel, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses in our internal control over financial reporting, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

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

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

Our certificate of incorporation designates the state courts in 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 discourage lawsuits against the company and our directors, officers and employees.

Our certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware does not have jurisdiction, the federal district court for the District of Delaware) will be the sole and exclusive forum for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, employees or stockholders to our company or our stockholders, (3) any action asserting a claim arising pursuant to any provision of the DGCL or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware or (4) any action asserting a claim arising pursuant to any provision of our certificate of incorporation or bylaws (in each case, as they may be amended from time to time) or governed by the internal affairs doctrine. This exclusive forum provision will not apply to actions arising under the Securities Act or the Securities Exchange Act of 1934, as amended.

This exclusive forum provision may limit the ability of our stockholders to bring a claim in a judicial forum that such stockholders find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees. Alternatively, if a court were to find the choice of forum provision contained in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could materially adversely affect our business, financial condition and operating results.

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

Not applicable.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

(a) None.

(b) None.

(c) ***Director and Officer Trading Plans and Arrangements***

None.

Item 6. Exhibits.

Exhibit Number	Description
3.1	Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 22, 2019).
3.2	Certificate of Amendment of the Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 9, 2023).
3.3	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 22, 2019).
10.1*†	Collaboration and License Agreement, dated as of May 11, 2024, by and between the Registrant and Genzyme Corporation, Inc, a wholly-owned subsidiary of Sanofi.
10.2*	Third Amendment to 2022 Inducement Stock Incentive Plan, effective as of June 17, 2024.
10.3*†	Second Amendment to Collaboration and License Agreement, effective as of July 24, 2024, by and between the Registrant and MyoKardia, Inc, a wholly-owned subsidiary of Bristol Myers Squibb Company.
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1+	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2+	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104	Cover Page Interactive Data File (formatted as Inline XBRL with applicable taxonomy extension information contained in Exhibits 101).

* Filed herewith.
# Management contract or compensatory plan or arrangement.
† Certain portions of this exhibit have been omitted because the registrant has determined that they are both not material and is the type of information that the registrant treats as private or confidential.
+ Furnished herewith.

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.

FULCRUM THERAPEUTICS, INC.

Date: July 31, 2024 By: /s/ Alex C. Sapir
Alex C. Sapir
President and Chief Executive Officer (Principal Executive Officer)

Date: July 31, 2024 By: /s/ Alan Musso
Alan Musso
Chief Financial Officer (Principal Financial Officer)

Exhibit 10.1

CERTAIN INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL

COLLABORATION AND LICENSE AGREEMENT

BY AND BETWEEN

FULCRUM THERAPEUTICS INC.

AND

GENZYME CORPORATION

Dated May 11, 2024

TABLE OF CONTENTS

SCHEDULES

COLLABORATION AND LICENSE AGREEMENT

This **COLLABORATION AND LICENSE AGREEMENT** (this "**Agreement**") is made and entered into as of May 11, 2024 (the "**Effective Date**") between Fulcrum Therapeutics Inc., a Delaware corporation ("**Fulcrum**"), having a place of business at 26 Landsdowne Street, Cambridge, Massachusetts 02139, and Genzyme Corporation, a company organized and existing under the laws of the state of Massachusetts, having a place of business at 450 Water Street, Cambridge, MA 02411 ("**Sanofi**"). Fulcrum and Sanofi may be referred to in this Agreement individually as a "**Party**" and collectively as the "**Parties**."

RECITALS

WHEREAS, Fulcrum is a clinical-stage biopharmaceutical company engaged in the research and development of medicines for the treatment of genetically defined rare diseases, including selective p38α/β mitogen activated protein kinase ("**MAPK**") inhibitors for the treatment of facioscapulohumeral muscular dystrophy ("**FSHD**");

WHEREAS, Fulcrum Controls certain Know-How and Patent Rights relating to such proprietary compounds;

WHEREAS, Sanofi (itself and through its Affiliates) has expertise in the development of biopharmaceutical products and has regulatory, development, and commercial capabilities in the Sanofi Territory; and

WHEREAS, the Parties desire to collaborate to Exploit the Licensed Products, and Fulcrum wishes to grant Sanofi and Sanofi wishes to receive an exclusive license to Exploit the Licensed Products in the Sanofi Territory, in each case, as set forth in, and subject to the terms of, this Agreement.

NOW THEREFORE, the Parties agree as follows:

ARTICLE 1
DEFINITIONS

1.1 "**Accounting Standards**" means with respect to a Party or its Affiliate or Sublicensee, GAAP or IFRS, as such Party, Affiliate or Sublicensee uses for its financial reporting obligations, in each case, consistently applied.

1.2 "**Acquisition Transaction**" has the meaning set forth in Section 2.7.2 (*Acquisition of a Competitive Product*).

1.3 "**Additional Activity**" has the meaning set forth in Section 5.3.1(a) (*Additional Activities under Global Development Plan*).

1.4 "**Additional Compound**" has the meaning set forth in Section 5.3.2 (*Development of Additional Licensed Compounds*).

1.5 "**Additional LC Activities**" has the meaning set forth in Section 5.3.2 (*Development of Additional Licensed Compounds*).

1.6 "**Affiliate**" means, with respect to a Person, any other Person controlled by, controlling, or under common control with such Person, for so long as such Person is controlled by, is controlling, or is under common control with such other Person. The term "control" (including, with correlative

meanings, the terms “controlled by” and “under common control with”) as used with respect to a Person means (a) direct or indirect beneficial ownership of [***] of the voting stock or other ownership interest of such Person, or (b) the possession, directly or indirectly, of the power to direct the management or policies of such Person, whether through the ownership of voting securities or other equity rights, by contract relating to voting rights or corporate governance, or otherwise.

1.7 “**Agreement**” has the meaning set forth in the Preamble.

1.8 “**Alliance Manager**” has the meaning set forth in Section 3.9 (*Alliance Managers*).

1.9 “**Allowable Overruns**” means any Global Development Costs incurred by or on behalf of a Party or its Affiliates in any Calendar Year that are above the then-current Global Development Budget for such Calendar Year by [***] or less.

1.10 “**Applicable Law**” means collectively all laws, statues, rules, regulations, ordinances, decrees, judicial and administrative orders (and any license, franchise, permit, or similar right granted under any of the foregoing), and any policies and other requirements of any applicable Governmental Authority that govern or otherwise apply to a Party or the activities contemplated herein, including: (a) to the extent applicable, GCP, GLP and GMP; (b) all applicable data protection and privacy laws, rules and regulations, including, to the extent applicable, the United States Department of Health and Human Services privacy rules under the Health Insurance Portability and Accountability Act and the Health Information Technology for Economic and Clinical Health Act and the EU Data Protection Directive (Council Directive 95/46/EC) and applicable laws implementing the EU Data Protection Directive and the General Data Protection Regulation (2016/679); and (c) written governmental interpretations, the guidance related to or the application of, any of the foregoing.

1.11 “**Approved Labeling**” means, with respect to a Licensed Product and a jurisdiction: (a) the applicable Regulatory Authority-approved full prescribing information for such Licensed Product in such jurisdiction; and (b) the applicable Regulatory Authority-approved labels and other written, printed, or graphic materials on any container, wrapper, or any package insert that is used with or for such Licensed Product in such jurisdiction.

1.12 “**Arbitrator**” has the meaning set forth in Section 15.1.3 (*Dispute Resolution*).

1.13 “**Asian Region**” means all countries and territories of Asia other than (a) Japan, (b) the Russian Federation, and (c) the Middle Eastern Countries.

1.14 “**Auditor**” has the meaning set forth in Section 9.7.2 (*Audit Rights*).

1.15 “**Background Know-How**” has the meaning set forth in Section 10.1.1 (*Ownership of Background Technology*).

1.16 “**Background Patents**” has the meaning set forth in Section 10.1.1 (*Ownership of Background Technology*).

1.17 “**Background Technology**” has the meaning set forth in Section 10.1.1 (*Ownership of Background Technology*).

1.18 “**Budget Overrun**” has the meaning set forth in Section 5.7.1 (*Eligible Global Development Costs*).

1.19 "**Business Day**" means a day other than a Saturday, Sunday, or a day on which banking institutions in Boston, Massachusetts; Bridgewater, New Jersey; or Paris, France are authorized or required by Applicable Law to remain closed. In addition, none of December 26 through December 31 (inclusive) shall constitute a Business Day.

1.20 "**Calendar Quarter**" means each of the three (3)-month periods ending March 31, June 30, September 30 and December 31; *except* that (a) the first Calendar Quarter during the Term will begin on the Effective Date and end on the last day of the Calendar Quarter within which the Effective Date falls, and (b) the last Calendar Quarter during the Term will end upon the expiration of the Term.

1.21 "**Calendar Year**" means the period of twelve (12) consecutive calendar months beginning on January 1 and ending on December 31; *except* that (a) the first Calendar Year during the Term will begin on the Effective Date and end on December 31 of the Calendar Year within which the Effective Date falls, and (b) the last Calendar Year during the Term will end upon expiration of the Term.

1.22 "**Change of Control**" means, with respect to a Party, that: (a) any Third Party acquires, in one or more related transactions, directly or indirectly the beneficial ownership of any voting security of such Party, or if the percentage ownership of such Third Party in the voting securities of such Party is increased through stock redemption, cancellation, or other recapitalization, and immediately after such acquisition or increase such Third Party is, directly or indirectly, the beneficial owner of voting securities representing [***] of the total voting power of all of the then outstanding voting securities of such Party; (b) a merger, consolidation, recapitalization, or reorganization of such Party is consummated that would result in shareholders or equity holders of such Party immediately prior to such transaction owning [***] or less of the outstanding voting securities of the surviving entity (or its parent entity) immediately following such transaction; or (c) the sale or transfer to a Third Party, in one or more related transactions, of all or substantially all of such Party's assets relating to the subject matter of this Agreement.

1.23 "**Clinical Trial**" means any clinical trial in humans, as that term is defined in FDA regulations at 21 C.F.R. § 312.3, or a similar clinical investigation conducted on human subjects, as defined under Applicable Law outside the United States. Without limiting the foregoing, "Clinical Trial" includes any Phase 3 Clinical Trial.

1.24 "**CMO**" means a Third Party contract manufacturing organization.

1.25 "**Co-Defending Party**" has the meaning set forth in Section 10.5.4 (*Cooperation*).

1.26 "**Code**" has the meaning set forth in Section 14.6.1 (*Termination Right*).

1.27 "**Collaboration In-License**" means (a) any license deemed a "Collaboration In-License" under Section 2.6.2 (*New Collaboration In-Licenses*) and (b) any Existing Third Party IP Agreement.

1.28 "**Collaboration Know-How**" means all Know-How conceived, discovered, developed, invented or otherwise made by a Party's or its Affiliates', licensees', Sublicensees', or subcontractors' employees, agents, or independent contractors, or any Persons contractually required to assign or license such Know-How to such Party or any Affiliate of such Party, either alone or jointly with the other Party's or its Affiliates', licensees', Sublicensees', or subcontractors' employees, agents, or independent contractors, or any Persons contractually required to assign or license such

Know-How to such other Party or any Affiliate of such other Party, in each case, in the performance of activities under this Agreement during the Term.

1.29 "**Collaboration Patent Rights**" means any Patent Right that Covers any Invention included in the Collaboration Know-How.

1.30 "**Collaboration Technology**" means the Collaboration Know-How and the Collaboration Patent Rights.

1.31 "**Combination Product**" means a Licensed Product that: (a) contains one or more Licensed Compounds and one or more Other Active Ingredients, sold as a fixed dose/unit, for which no royalty would be due hereunder if such Other Active Ingredient were sold separately; (b) consists of one or more Licensed Compounds and sold as separate doses/units in a single package, or otherwise co-packaged or combined, with one or more Other Components for which no royalty would be due hereunder if such Other Components were sold separately, and such Licensed Compounds and Other Components are sold for a single price; or (c) is defined as a "combination product" by the FDA pursuant to 21 C.F.R. 3.2(e) or its foreign equivalent.

1.32 "**Commercialization**" means any and all activities directed to the commercialization of a product, including: marketing; detailing; promotion; market research; distributing; order processing; handling returns and recalls; booking sales; customer service; administering and commercially selling such product; importing, exporting and transporting such product for commercial sale; and seeking Reimbursement Approval of a product (if applicable), in each case, whether before or after Regulatory Approval has been obtained for such product, as well all regulatory compliance with respect to the foregoing. "**Commercializing**," "**Commercialize,**" and "**Commercialized**" will be construed accordingly.

1.33 "**Commercially Reasonable Efforts**" means, (a) with respect to Sanofi's or its Affiliates' obligations under this Agreement, on a country-by-country basis, the carrying out of such obligations or tasks with a level of efforts and resources (including departmental budget resources) consistent with the efforts and resources that [***]; or (b) with respect to Fulcrum's or its Affiliates' obligations under this Agreement, the carrying out of such obligations or tasks with a level of efforts and resources (including departmental budget resources) consistent with the efforts and resources that [***]. Commercially Reasonable Efforts requires [***]. To the extent that the performance of a Party's obligations hereunder is adversely affected by the other Party's failure to perform its obligations hereunder, the impact of such performance failure will be taken into account in determining whether such Party has used its Commercially Reasonable Efforts to perform any such affected obligations.

1.34 "**Competitive Infringement**" has the meaning set forth Section 10.3.1 (*Notice of Infringement or Misappropriation*).

1.35 "**Competitive Product**" has the meaning set forth in Section 2.7.1 (*Exclusivity Obligations*).

1.36 "**Confidential Disclosure Agreement**" has the meaning set forth in Section 16.2 (*Entire Agreement; Amendment*).

1.37 "**Confidential Information**" means (a) Know-How and any non-public or proprietary technical, scientific, trade, research, manufacturing, business, financial, marketing, product, supplier, intellectual property, and other data or information (including unpublished patent applications) that may be disclosed by one Party or its Affiliates to the other Party or its Affiliates pursuant to this

Agreement (including information disclosed prior to the Effective Date pursuant to the Confidential Disclosure Agreement), regardless of whether such information is specifically marked or designated as confidential and regardless of whether such information is in written, oral, electronic, or other form, and (b) the terms of this Agreement.

1.38 "**Continuing Technology Transfer**" has the meaning set forth in Section 4.2 (*Continuing Technology Transfer*).

1.39 "**Controlled**" means the possession by a Party (whether by ownership, license, or otherwise other than pursuant to this Agreement) of, (a) with respect to any materials or other tangible Know-How, the legal authority or right to physical possession of such materials or tangible Know-How, with the right to provide such materials or tangible Know-How to the other Party on the terms set forth herein, and (b) with respect to Patent Rights, Regulatory Approvals, Regulatory Submissions, intangible Know-How, or other intellectual property, the legal authority or right to grant a license, sublicense, access, or right to use (as applicable) to the other Party under such Patent Rights, Regulatory Approvals, Regulatory Submissions, intangible Know-How, or other intellectual property on the terms set forth herein, in each case ((a) and (b)), without breaching or otherwise violating the terms of any arrangement or agreement with a Third Party in existence as of the time such Party or its Affiliates would first be required hereunder to grant the other Party such access, right to use, licenses, or sublicense or incurring any additional payment obligations to a Third Party as a result of such access, right to use, licenses, or sublicense, other than payment obligations incurred under a Collaboration In-License.

Notwithstanding the foregoing, and subject to the following paragraph, in the event a Party undergoes a Change of Control (where such Party is the acquired entity), then such Party or its Affiliates will not be deemed to "Control" any of the foregoing (a) or (b) that:

(i) prior to the consummation of such Change of Control, is owned or in-licensed by a Third Party that becomes an Affiliate of such acquired Party or any of such Third Party's Affiliates existing immediately prior to such Change of Control (or that merges or consolidates with such Party) after the Effective Date as a result of such Change of Control, or

(ii) after the consummation of such Change of Control, is developed or in-licensed by such Third Party or its pre-existing Affiliates without use of or access to any Patent Rights, Know-How or Confidential Information of either Party (including any Patent Rights, Know-How, or Confidential Information licensed or acquired from the other Party under this Agreement).

However, a Party or its Affiliates *will* be deemed to "Control" any of the foregoing ((a) and (b)), if:

(A) prior to the effective date of such Change of Control, such Party or its Affiliate also Controlled such subject matter of such Third Party;

(B) such subject matter was conceived, developed or otherwise arises from participation by employees or consultants of such Third Party, such Party or its Affiliates in the performance of activities under this Agreement or otherwise in relation to Licensed Compounds or Licensed Products after such Change of Control; or

(C) such subject matter was not used in the performance of activities under this Agreement or otherwise in relation to Licensed Compounds or Licensed Products prior to the effective date of such Change of Control but after the effective date of such Change of Control, such Party or its

Affiliate uses such subject matter in the performance of its obligations or exercise of its rights under this Agreement or otherwise in relation to Licensed Compounds or Licensed Products.

1.40 "**Core Third Party IP**" means any Patent Right, Know-How or other intellectual property right of a Third Party that [***].

1.41 "**Cover**" means, with respect to a particular subject matter at issue and a relevant Patent Right or individual claim in such Patent Right, as applicable, that the Exploitation of such subject matter, without taking into account any exemption under Applicable Law, would infringe such Patent Right or individual claim in such Patent Right in the country in which such activity occurs without a license thereto or ownership thereof.

1.42 "**CREATE Act**" has the meaning set forth in Section 10.1.3(c) (*CREATE Act*).

1.43 "**Debarred/Excluded**" has the meaning set forth in Section 11.1.8 (*Mutual Representations and Warranties*).

1.44 "**Defending Party**" has the meaning set forth in Section 10.5.4 (*Cooperation*).

1.45 "**Derivative**" means, with respect to a compound, any ester, salt, free acid form, free base form, amorphous, crystalline, solvate, hydrate, co-crystal, chelate, deuterated, racemate, stereoisomer, tautomer, prodrug variation of such compound.

1.46 "**Development**" means all clinical drug development activities and other development activities with respect to a product, including: Clinical Trials (and other trials commenced after Regulatory Approval); test method development and stability testing; toxicology; formulation; process development; qualification; validation; quality assurance and quality control; statistical analysis and report writing; the preparation and submission of INDs and MAAs; medical and regulatory affairs with respect to the foregoing; and all other activities requested or required by a Regulatory Authority or as a condition or in support of obtaining or maintaining a Regulatory Approval for a product. For clarity, "Development" does not include Research, Manufacturing or Commercialization. "**Developing**," and "**Developed**" will be construed accordingly.

1.47 "**Disclosing Party**" has the meaning set forth in Section 12.1.1 (*Duty of Confidence*).

1.48 "Distributor" means any Third Party (a) to which Sanofi, its Affiliates or Sublicensees has granted a right to market, resell or distribute a Licensed Product, and (b) that does not make payments to Sanofi, its Affiliates or Sublicensees that are calculated on the basis of a percentage of, or profit share on, such Third Party's sales of Licensed Product.

1.49 "**Divestiture**" means, with respect to a Competitive Product, the sale, exclusive license, or other transfer by Fulcrum and its Affiliates of all of its and their Research, Development, Manufacturing, and Commercialization rights with respect to such Competitive Product to a Third Party without the retention or reservation of any Research, Development, Manufacturing, or Commercialization interest or participation rights (other than as permitted under Applicable Law, solely an economic interest or the right to enforce customary terms and conditions contained in the relevant agreements effectuating such divestiture).

1.50 "**Divest**" means to effect a Divestiture.

1.51 "**Effective Date**" has the meaning set forth in the Preamble.

1.52 "**Eligible Global Development Costs**" means (a) the Global Development Costs incurred by or on behalf of a Party or its Affiliates in accordance with the Global Development Plan and the amount budgeted therefor in the Global Development Budget, *plus* applicable Allowable Overruns or other expenses approved by the JSC and (b) the Manufacturing Costs for all Licensed Compounds and Licensed Products required for either Party's activities under the Global Development Plan.

1.53 "**EMA**" means the European Medicines Agency or any successor agency thereto.

1.54 "**Enforcing Party**" has the meaning set forth in Section 10.3.4 (*Cooperation*).

1.55 "**EO Dispute Resolution Period**" has the meaning set forth in Section 15.1.1 (*Dispute Resolution*).

1.56 "**EPO**" has the meaning set forth in Section 10.2.2(b) (*Review and Consult*).

1.57 "**Establishing Committee**" has the meaning set forth in Section 3.5.3 (*Operational Teams*).

1.58 "**European Region**" means all members of the European Union or the European Economic Area (EEA) as of the Effective Date, other than (a) France, (b) Germany, (c) Italy, (d) Spain, and (e) the Netherlands.

1.59 "**European Union**" or "**E.U.**" means the economic, scientific, and political organization of member states of the European Union as it may be constituted from time to time.

1.60 "**Executive Officer**" means (a) with respect to Fulcrum, the Chief Executive Officer of Fulcrum or his/her designee or successor with appropriate decision-making authority (as of the Effective Date such individual is [***]); and (b) with respect to Sanofi, (i) in the case of any disputes relating to the Development of Licensed Compounds or Licensed Products (including the Manufacture of Licensed Compounds and Licensed Products in support of Development activities hereunder), the Head of Rare Disease Development or his/her designee or successor with appropriate decision-making authority (as of the Effective Date such individual is [***]), and (ii) in the case of any disputes relating to the Commercialization of Licensed Compounds or Licensed Products (including the Manufacture of Licensed Compounds and Licensed Products in support of Commercialization activities hereunder), the Global Head of Rare Disease or his/her designee or successor with appropriate decision-making authority (as of the Effective Date such individual is [***]).

1.61 "**Existing Third Party IP Agreement**" means any agreement identified in **Schedule 1.61** (*Existing Third Party IP Agreement*) between Fulcrum (or any of its Affiliates) and any Third Party entered into prior to the Effective Date under which such Third Party grants Fulcrum (or any of its Affiliates) a license to any of the Fulcrum Technology that is sublicensed to Sanofi hereunder as of the Effective Date.

1.62 "**Exploit**" means to make, have made, use, have used, import, have imported, export, have exported, offer to sell, have offered to sell, sell, have sold, Research, have Researched, Develop, have Developed, Manufacture, have Manufactured, perform medical affairs activities for, have performed medical affairs activities for, Commercialize, have Commercialized or otherwise exploit or have exploited. "**Exploitation**" will be construed accordingly.

1.63 "**External Costs**" mean reasonable, out-of-pocket costs and expenses actually paid to Third Parties and accrued in accordance with Accounting Standards by a Party (or its Affiliate) in consideration

of the performance of activities under this Agreement, and excluding any costs or expenses included under the FTE Rate.

1.64 "**Falsified Medicine**" has the meaning set forth in Section 10.12.1 (*Notification*).

1.65 "**FD&C Act**" means the United States Federal Food, Drug and Cosmetic Act, as amended from time-to-time, together with any rules, regulations, and requirements promulgated thereunder (including all additions, supplements, extensions, and modifications thereto).

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

1.67 "**Field**" means any and all uses in all indications, *except* in the context of the GSK Patent Rights with respect to which any reference to the Field shall mean all therapeutic uses in humans.

1.68 "**Firewall Procedures**" has the meaning set forth in Section 2.7.2 (*Acquisition of a Competitive Product*).

1.69 "**First Commercial Sale**" means, on a Licensed Product-by-Licensed Product and country-by-country basis, the first sale of such Licensed Product for monetary value in such country to a Third Party for use or consumption by an end user following receipt of all Regulatory Approvals that are required in order to sell such Licensed Product in such country; *provided*, *however*, that the following will not constitute a First Commercial Sale: (a) any sale to any of Sanofi's Affiliates or Sublicensees, unless such Affiliate or Sublicensee is the last Person in the distribution chain of the Licensed Product; (b) any use by or on behalf of Sanofi or its Affiliates or Sublicensees of such Licensed Product in Clinical Trials or non-clinical development activities; or (c) any disposal or transfer of such Licensed Product for a *bona fide* charitable purpose, compassionate use or as sample; *provided* that the consideration received by Sanofi, its Affiliates or Sublicensees for such disposal or transfer is no more than the cost of goods for such Licensed Product plus a reasonable margin to compensate Sanofi for overhead costs related to the Manufacture of such Licensed Product.

1.70 "**Force Majeure Event**" has the meaning set forth in Section 16.6 (*Force Majeure*).

1.71 "**FSHD**" has the meaning set forth in the Recitals.

1.72 "**FTE**" means the equivalent of the work of one duly qualified employee of a Party full time for one year (consisting of a total of [***] working hours per year) carrying out Development activities under this Agreement. Overtime, and work on weekends, holidays and the like will not be counted with any multiplier (*e.g.*, time-and-a-half or double time) toward the number of hours that are used to calculate the FTE contribution, and no individual may be charged at greater than one FTE, regardless of that individual's hours worked during that year. The portion of an FTE billable by a Party for one employee during a given accounting period will be determined by dividing the number of hours worked directly by such employee on the work to be conducted under this Agreement during such accounting period by the number of FTE hours applicable for such accounting period based on [***] working hours per Calendar Year.

1.73 "**FTE Rate**" means the rate of [***] per FTE per Calendar Year. Each FTE Rate will be prorated for the period beginning on the Effective Date and ending on December 31, 2024, and is subject to annual adjustment in each Calendar Year during the Term by the percentage increase or decrease in the Consumer Price Index published by the U.S. Bureau of Labor Statistics as of December 31 of each Calendar Year, over the level of such Consumer Price Index as of December 31 of the prior

Calendar Year, with the first such increase or decrease to be effective on January 1, 2025, or any other index as agreed upon by the Parties through the JSC. For the avoidance of doubt, such FTE Rate will be the fully-burdened rate and is intended to cover the cost of salaries, employee benefits, infrastructure costs, travel, general laboratory or office supplies, postage, insurance, training, and all other general expenses and overhead items, in each case, expended in connection with relevant activities.

1.74 "**Fulcrum**" has the meaning set forth in the Preamble.

1.75 "**Fulcrum Development Cost Share Notice**" has the meaning set forth in Section 5.7.1 (*Eligible Global Development Costs*).

1.76 "**Fulcrum Indemnitees**" has the meaning set forth in Section 13.2 (*Indemnification by Sanofi*).

1.77 "**Fulcrum Independent Development Activities**" has the meaning set forth in Section 5.2 (*Initial Global Development Plan*).

1.78 "**Fulcrum Independent Development Plan**" has the meaning set forth in Section 5.6 (*Fulcrum Independent Development Plan*).

1.79 "**Fulcrum Independent Development Program**" means the program of Development activities conducted under the Fulcrum Independent Development Plan, which, for clarity, will exclude any Development activities conducted under the Global Development Program or the Sanofi Independent Development Program.

1.80 "**Fulcrum Know-How**" means, subject to Section 5.3.1(c)(iii) (*Additional Activities under Global Development Plan*), all Know-How (excluding Fulcrum's interest in Joint Collaboration Know-How) that is (a) Controlled by Fulcrum or any of its Affiliates as of the Effective Date or during the Term and (b) necessary or reasonably useful to Exploit a Licensed Compound or Licensed Product in the Field.

1.81 "**Fulcrum Manufacturing Technology**" has the meaning set forth in Section 8.3 (*Manufacturing Technology Transfer*).

1.82 "**Fulcrum Materials**" means any assays, biological substances (and any constituents, progeny, mutants, derivatives, or replications thereof or therefrom), chemical compounds, or other tangible materials (a) Controlled by Fulcrum or any of its Affiliates, (b) in the possession of Fulcrum, any of its Affiliates, or any of its subcontractors acting on behalf of Fulcrum under this Agreement as of the Effective Date or during the Term, and (c) (i) related to any Licensed Compound or Licensed Product or (ii) otherwise necessary or reasonably useful for the Research, Development, Manufacture, Commercialization or other Exploitation of any Licensed Compound or Licensed Product.

1.83 "**Fulcrum Patent Rights**" means all Patent Rights (excluding Fulcrum's interest in Joint Collaboration Patent Rights) that are (a) Controlled by Fulcrum or any of its Affiliates as of the Effective Date or during the Term and (b) necessary or reasonably useful (or, with respect to patent applications, would be necessary or reasonably useful if such patent applications were to issue as patents) to Exploit a Licensed Compound or Licensed Product in the Field. All Fulcrum Patent Rights as of the Effective Date are set forth on **Schedule 1.83** (*Fulcrum Patent Rights*); *provided* that, any Patent Right existing as of the Effective Date that otherwise would be included in the

definition of Fulcrum Patent Rights but is not included on **Schedule 1.83** (*Fulcrum Patent Rights*) will still be considered a Fulcrum Patent Right.

1.84 "**Fulcrum Product Trademarks**" has the meaning set forth in Section 10.11.1(b) (*Ownership of Fulcrum Product Trademarks*).

1.85 "**Fulcrum Prosecuted Patent Rights**" has the meaning set forth in Section 10.2.1(a) (*Right to Prosecute*).

1.86 "**Fulcrum Sponsored Clinical Trial**" means any Clinical Trial under the Global Development Plan for which Fulcrum is the sponsor, including the Global Phase 3 REACH Study.

1.87 "**Fulcrum Technology**" means the Fulcrum Know-How, the Fulcrum Patent Rights, the Fulcrum Materials and Fulcrum's interest in the Joint Collaboration Technology.

1.88 "**Fulcrum Territory**" means the United States of America, including all territories and possessions thereof.

1.89 "**GAAP**" means the generally accepted accounting principles in the United States.

1.90 "**Generic Competition**" means, with respect to a Licensed Product in a country in the Sanofi Territory, [***].

1.91 "**Generic Product**" means, with respect to a Licensed Product in a country in the Sanofi Territory, a pharmaceutical product that: (a) is approved for use in such country pursuant to a regulatory approval process governing approval of a generic or biosimilar product of such Licensed Product based on the then-current standards for Regulatory Approval in such country, based upon all or part of the clinical data generated by the Parties pursuant to this Agreement or obtained using an abbreviated, expedited or other process; and (b) is sold in the same country as such Licensed Product by any Third Party that (i) is not a Sublicensee (other than a Sublicensee that has been granted a sublicense to any Licensed Product by Sanofi solely in connection with any settlement) and (ii) did not purchase such pharmaceutical product in a chain of distribution that included any of Sanofi, its Affiliates or its Sublicensees.

1.92 "**Global Development Budget**" has the meaning set forth in Section 5.2 (*Initial Global Development Plan*).

1.93 "**Global Development Costs**" means those External Costs incurred directly by or on behalf of a Party or its Affiliates in connection with the performance of any Research and Development activities for the Licensed Compounds and Licensed Products assigned to such Party under the Global Development Plan. In addition, Global Development Costs will include all Third Party payments made by a contracting Party or its Affiliate under a Collaboration In-License, to the extent allocable to or otherwise arising out of activities conducted under the Global Development Program. Global Development Costs will be recognized in accordance with the Accounting Standards.

1.94 "**Global Development Plan**" has the meaning set forth in Section 5.2 (*Initial Global Development Plan*).

1.95 "**Global Development Program**" means the program of Research and Development activities conducted under the Global Development Plan.

1.96 "**Global Phase 3 REACH Study**" means the ongoing Phase 3 Clinical Trial for a Licensed Product, with the clinical trial.gov identifier NCT05397470.

1.97 "**Global Trade Control Laws**" means the U.S. Export Administration Regulations, the U.S. International Traffic in Arms Regulations, the economic sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Control, E.U. Council Regulations on export controls, including Nos. 428/2009, 267/2012, other E.U. Council sanctions regulations, as implemented in the E.U. member states, United Nations sanctions policies, and all relevant regulations made under any of the foregoing.

1.98 "**Good Clinical Practices**" or "**GCP**" means the then-current good clinical practice standards, practices, and procedures promulgated or endorsed by the applicable Regulatory Authority as set forth in the guidelines imposed by such Regulatory Authority, as may be updated from time-to-time, that provide for, among other things, assurance that the clinical data and reported results are credible and accurate and protect the rights, integrity and confidentiality of trial subjects, including, as applicable: (a) as set forth in the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Harmonized Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95), as may be applicable from time to time; (b) as set forth in the Declaration of Helsinki (2004), as last amended at the 52nd World Medical Association in October 2000, as may be applicable from time to time; (c) as set forth in the U.S. Code of Federal Regulations Title 21, Parts 50 (Protection of Human Subjects), 56 (Institutional Review Boards) and 312 (Investigational New Drug Application), as may be applicable from time to time; and (d) the equivalent practices, standards and regulations promulgated or endorsed by the applicable Regulatory Authorities elsewhere in the Territory, as may be applicable from time to time, to the extent such standards are not less stringent than United States GCP.

1.99 "**Good Laboratory Practices**" or "**GLP**" means the then-current good laboratory practice standards, practices, and procedures promulgated or endorsed by the applicable Regulatory Authority as set forth in the guidelines imposed by such Regulatory Authority, as may be updated from time-to-time, including: (a) in the United States, those promulgated or endorsed by the FDA in U.S. 21 C.F.R. Part 58, as may be applicable from time to time; and (b) the equivalent practices, standards and regulations promulgated or endorsed by the applicable Regulatory Authorities outside the United States, as may be applicable from time to time, to the extent such practices, standards and regulations are not less stringent than United States GLP.

1.100 "**Good Manufacturing Practices**" or "**GMP**" means the then-current good manufacturing practice standards, practices, and procedures promulgated or endorsed by the applicable Regulatory Authority as set forth in the guidelines imposed by such Regulatory Authority, as may be updated from time-to-time, including, as applicable, as promulgated under and in accordance with: (a) the principles detailed in the U.S. Current Good Manufacturing Practices, 21 C.F.R. Parts 4, 210, 211, 601, 610 and 820, as may be applicable from time to time; (b) European Directive 2003/94/EC and EudraLex 4, as may be applicable from time to time; (c) the principles detailed in the International Conference on Harmonization's Q7 Guideline, as may be applicable from time to time; and (d) the equivalent practices, standards and regulations promulgated or endorsed by the applicable Regulatory Authorities elsewhere in the Territory, as may be applicable from time to time, to the extent such practices, standards and regulations are not less stringent than United States GMP.

1.101 "**Government Official**" means any official, officer, employee, or representative of: (a) any federal, state, provincial, administrative division, county, or municipal government or any department or agency thereof; (b) any public international organization or any department or agency thereof; or

(c) any company or other entity owned or controlled by any government or Governmental Authority.

1.102 "**Governmental Authority**" means any court, agency, department, authority, tribunal, or other instrumentality of any supra-national, national, state, provincial, county, city, or other political subdivision. For clarity, Governmental Authorities include all Regulatory Authorities.

1.103 "**GSK**" means collectively, (a) GlaxoSmithKline Intellectual Property (No. 2) Limited, a company organized under the laws of England and Wales and having a place of business at 980 Great West Road, Brentford, Middlesex TW8 9GS England, (b) GlaxoSmithKline LLC, a Delaware limited liability company having a place of business at 1250 S. Collegeville Road, Collegeville, PA 19426-0989, and (c) Glaxo Group Limited, a company organized under the laws of England and Wales and having a place of business at 980 Great West Road, Brentford, Middlesex TW8 9GS England.

1.104 "**GSK License Agreement**" means that certain Right of Reference and License Agreement by and between GSK and Fulcrum, effective as of February 8, 2019 and as amended by that First Amendment dated September 2020, and as may be further amended from time to time.

1.105 "**GSK Patent Rights**" means those Patent Rights licensed to Fulcrum under the GSK License Agreement.

1.106 "**GSK Side Letter**" means that certain letter agreement titled "Re: Collaboration and License Agreement with Genzyme Corporation", by and among GSK, Fulcrum and Sanofi, dated May 11, 2024.

1.107 "**IFRS**" means International Financial Reporting Standards, consistently applied.

1.108 "**IND**" means an Investigational New Drug application required pursuant to 21 C.F.R. Part 312 or any comparable filings outside of the U.S. required to commence human clinical trials in such country or region (such as an application for a Clinical Trial Authorization in the E.U.), and all supplements or amendments that may be filed with respect to the foregoing.

1.109 "**Indemnified Party**" has the meaning set forth in Section 13.3 (*Indemnification Procedure*).

1.110 "**Indemnifying Party**" has the meaning set forth in Section 13.3 (*Indemnification Procedure*).

1.111 "**Initial Global Development Plan**" has the meaning set forth in Section 5.2 (*Initial Global Development Plan*).

1.112 "**Initial Technology Transfer**" has the meaning set forth in Section 4.1 (*Initial Technology Transfer*).

1.113 "**Internal Costs**" means, for any period of time, the product obtained by *multiplying* (a) the actual total FTEs (or portion thereof) devoted to the performance of a required or permitted activity under this Agreement during such period *by* (b) the applicable FTE Rate for such period.

1.114 "**Invention**" means any process, method, composition of matter, article of manufacture, discovery, or finding that is conceived or reduced to practice (whether or not patentable).

1.115 "**IRS**" has the meaning set forth in Section 9.11.3 (*Tax Cooperation*).

1.116 "**JAMS**" has the meaning set forth in Section 15.1.2 (*Dispute Resolution*).

1.117 "**JAMS Rules**" has the meaning set forth in Section 15.1.2 (*Dispute Resolution*).

1.118 "**JCC**" has the meaning set forth in Section 3.4.1 (*Formation and Purpose of the JCC*).

1.119 "**JDC**" has the meaning set forth in Section 3.2.1 (*Formation and Purpose of the JDC*).

1.120 "**JMC**" has the meaning set forth in Section 3.3.1 (*Formation and Purpose of the JMC*).

1.121 "**Joint Collaboration Know-How**" means all Collaboration Know-How that is conceived, discovered, developed, invented or otherwise made jointly by a Party's or its Affiliates', licensees', Sublicensees', or subcontractors' employees, agents, or independent contractors, or any Persons contractually required to assign or license such Collaboration Know-How to such Party or any Affiliate of such Party, on the one hand, and the other Party's or its Affiliates', licensees', Sublicensees', or subcontractors' employees, agents, or independent contractors, or any Persons contractually required to assign or license such Collaboration Know-How to such Party or any Affiliate of such Party, on the other hand.

1.122 "**Joint Collaboration Patent Rights**" means all Collaboration Patent Rights that Cover Joint Collaboration Know-How.

1.123 "**Joint Collaboration Technology**" means the Joint Collaboration Know-How and the Joint Collaboration Patent Rights.

1.124 "**JSC**" has the meaning set forth in Section 3.1.1 (*Formation and Purpose of the JSC*).

1.125 "**Know-How**" means proprietary Inventions, discoveries, trade secrets, materials, information, experience, data, formulas, procedures, technology, and results (whether or not patentable), including practices, knowledge, know-how, experience and test data (including physical, chemical, biological, toxicological, pharmacological, clinical and veterinary data), dosage regimens, assays, diagnostics, product specifications, manufacturing techniques and costs, analytical and quality control data and marketing, pricing and distribution costs, and sales practices, methods, data, and descriptions, in each case, whether patentable or not, and, in each case, tangible manifestations thereof.

1.126 "**Knowledge**" means (a) with respect to Fulcrum, the actual knowledge of [***]; and (b) with respect to Sanofi, the actual knowledge of [***].

1.127 "**Latin American Region**" means the following countries and territories: all countries and territories of South America (excluding French Guiana), Mexico, Belize, Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, Panama, Cuba, Dominican Republic, and Haiti.

1.128 "**Launch Quarter**" has the meaning set forth in Section 9.3.2(b) (*Generic Competition*).

1.129 "**Licensed Compound**" means (a) Losmapimod or (b) any molecule that is Controlled by Fulcrum or its Affiliates as of the Effective Date or at any time during the Term, including any back-up compounds of Losmapimod, that binds or otherwise modulates p38a/b MAPK with a measured IC50 of <50 nM in an established FSHD cell model-based assay that measures the reduction in MBD3L2 gene expression (normalized to POLR2A gene expression), as demonstrated in the Rojas, LA, et al. (2020). p38 α Regulates Expression of DUX4 in a Model of Facioscapulohumeral

Muscular Dystrophy. J Pharmacol Exp Ther. Sep;374(3):489-498. doi:10.1124/jpet.119.264689 publication; and (c) any Derivatives of such compounds described in the foregoing clauses (a) or (b).

1.130 "**Licensed Product**" means any product containing a Licensed Compound as an active pharmaceutical ingredient, in any and all forms, presentations, delivery systems, dosages and formulations, alone or in combination with one or more Other Active Ingredients.

1.131 "**Licensed Sanofi Technology**" has the meaning set forth in Section 2.6.2(b)(ii) (*New Collaboration In-Licenses*) and Section 2.11 (*Licensed Sanofi Technology*).

1.132 "**Losmapimod**" means that certain product candidate designated by Fulcrum as of the Effective Date as "Losmapimod", as further described on **Schedule 1.132** (*Losmapimod*).

1.133 "**Losses**" has the meaning set forth in Section 13.1 (*Indemnification by Fulcrum*).

1.134 "**MAA**" or "**Marketing Authorization Application**" means any (a) Biologics License Application submitted under Section 351(a) of the PHSA, (b) New Drug Application as defined in the FD&C Act, or (c) substantially similar application or submission to those set forth in clause (a) or clause (b) filed with a Regulatory Authority in a country or group of countries to obtain Regulatory Approval to Commercialize a biopharmaceutical or diagnostic product in that country or in that group of countries, including, with respect to the E.U., a Marketing Authorization Application filed with the EMA pursuant to the centralized approval procedure or with the applicable Regulatory Authority of a country in the E.U. with respect to the mutual recognition or any other national approval, in each case ((a) through (c)), including any amendments thereto, and supplemental applications, but excluding Reimbursement Approval applications.

1.135 "**Manufacture**" means all activities related to the manufacturing of a compound or product or any component or ingredient thereof, including: (a) the production, manufacture, having manufactured, processing, filling, finishing, packaging, labeling, shipping and holding of product or any intermediate thereof; and (b) process development; process qualification and validation; scale-up; commercial manufacture; analytic development; product characterization; stability testing; and quality assurance and quality control. "**Manufacturing**" and "**Manufactured**" will be construed accordingly.

1.136 "**Manufacturing Costs**" means, with respect to a Licensed Compound or Licensed Product, the direct costs incurred by a Party or its Affiliates in Manufacturing such Licensed Compound or Licensed Product, which shall equal the sum of the following as incurred for such Licensed Compound or Licensed Product: [***].

1.137 "**Manufacturing Technology Transfer**" has the meaning set forth in Section 8.3 (*Manufacturing Technology Transfer*).

1.138 "**Manufacturing Technology Transfer Agreement**" has the meaning set forth in Section 8.3 (*Manufacturing Technology Transfer*).

1.139 "**MAPK**" has the meaning set forth in the Recitals.

1.140 "**Material Adverse Effect**" means, with respect to a Party, any event, occurrence, condition, change, circumstance, development, effect or state of facts that has or will have, individually or in the aggregate, a material adverse effect with respect to the Research, Development, Manufacture,

Commercialization or other Exploitation of a Licensed Compound or Licensed Product in such Party's Territory or (b) the ability of such Party to obtain or maintain Regulatory Approval or Reimbursement Approval for a Licensed Product in such Party's Territory.

1.141 "**Material Delay**" means any event or condition (or related series of events or conditions) that causes or otherwise results in a delay (or total stoppage) in the progress of the Global Development Plan of more than [***] except (a) for any event or condition outside the reasonable control of Fulcrum that is not directly related to a breach by Fulcrum of this Agreement; (b) if such event or condition is substantially a result of any inaction or action by Sanofi, its Affiliates or Sublicensees; (c) if such event or condition is a result of Fulcrum's reasonable response to guidance from or action or inaction by a Regulatory Authority or Governmental Authority (such as a clinical hold, recall or withdrawal); (d) for a Force Majeure Event; or (e) for any delay or stoppage mutually agreed upon by the Parties.

1.142 "**MHLW**" has the meaning set forth in Section 1.175 (*Definition of Regulatory Authority*).

1.143 "**MHRA**" means the Medicines and Healthcare products Regulatory Agency in the United Kingdom, or any successor agency thereto.

1.144 "**Middle Eastern Countries**" means the following countries and territories: Bahrain, Egypt, Iran, Iraq, Israel, Jordan, Kuwait, Lebanon, Oman, the Palestinian territories, Qatar, Saudi Arabia, Syria, Turkey, United Arab Emirates, and Yemen.

1.145 "**Milestone Events**" means the Regulatory Milestone Events and Sales Milestone Events.

1.146 "**Milestone Payments**" means the Regulatory Milestone Payments and Sales Milestone Payments.

1.147 "**Net Sales**" means, with respect to a Licensed Product for any period, the gross amount invoiced by Sanofi or any of its Affiliates or Sublicensees for the sale of such Licensed Product in arm's length transactions to a Third Party commencing with the First Commercial Sale on a country-by-country basis of such Licensed Product, less the following deductions determined in accordance with the Accounting Standards of Sanofi, its Affiliate or Sublicensee, as applicable, from such gross amounts which are actually incurred, allowed, paid, accrued or specifically allocated, with respect to such Licensed Product over such period:

1.147.1 [***]

1.147.2 [***]

1.147.3 [***]

1.147.4 [***]

1.147.5 [***]

1.147.6 [***]

1.147.7 [***]

1.147.8 [***]

1.147.9 [***]

1.147.10 [***]

For the avoidance of doubt, if a single item falls into more than one of the categories set forth in Section 1.147.1 through Section 1.147.10 above, such item may not be deducted more than once. Any of the deductions listed above that involves a payment by Sanofi, its Affiliates or its Sublicensees will be taken as a deduction in the Calendar Quarter in which the payment is accrued by such entity. For purposes of determining Net Sales, a Licensed Product will be deemed to be sold when it has met the applicable Accounting Standard's revenue recognition criteria. Net Sales will not include transfers or dispositions of such Licensed Product for pre-clinical or clinical purposes, compassionate use, special access programs or named patient programs, donations or as samples. Such Party's, its Affiliates' or its Sublicensees' transfer of any Licensed Product to an Affiliate or Sublicensee will not result in any Net Sales unless the transferee is the last Person in the distribution chain of the Licensed Product.

In the event that a Licensed Product is sold in any country in the form of a Combination Product, Net Sales of such Combination Product will be adjusted by multiplying actual Net Sales of such Combination Product in such country calculated pursuant to the foregoing definition of "Net Sales" by the fraction A/(A+B), where A is the average net invoice price in such country of any Licensed Product that contains the same Licensed Compound(s) as such Combination Product as its sole active ingredient(s), if sold separately in such country, and B is the average net invoice prices in such country of, as applicable, each product that contains the Other Component(s) as its sole component, if sold separately in such country; *provided* that the invoice price in a country for (i) each Licensed Product that contains solely the Licensed Compound(s) and (ii) in the case of a product that contains solely the Other Component(s), in each case, will to the extent feasible be for a quantity comparable to that used in such Combination Product and of substantially the same class, purity and potency or functionality, as applicable. If either such Licensed Product that contains the Licensed Compound(s) as its sole active ingredient or any such product that contains the Other Component(s) as its sole component is not sold separately (including in the case of the sale of a combination therapy that contains the Licensed Compound but is not sold separately) in a particular country, then the adjustment to Net Sales will be determined by [***] in good faith to reasonably reflect the fair market value of the contribution of such Licensed Compound or Other Component(s) in such Combination Product to the total fair market value of such Combination Product.

In the case of pharmacy incentive programs, hospital performance incentive programs, chargebacks, disease management programs, and similar programs or discounts on portfolio product offerings, all rebates, discounts and other forms of reimbursements will be allocated among products on the basis on which such rebates, discounts and other forms of reimbursements were actually granted or, if such basis cannot be determined, in accordance with Sanofi's, its Affiliates' or its Sublicensees' existing allocation method; provided that any such allocation will be done in accordance with Applicable Law, including any price reporting laws, rules and regulations.

Subject to the above, Net Sales will be calculated in accordance with the standard internal policies and procedures of Sanofi, its Affiliates or Sublicensees, which must be in accordance with applicable Accounting Standards.

1.148 "**New Third Party IP Agreement**" has the meaning set forth in Section 2.6.2 (*New Collaboration In-Licenses*).

1.149 "**New Third Party IP Rights**" has the meaning set forth in Section 2.6.2 (*New Collaboration In-Licenses*).

1.150 "**Non-Enforcing Party**" has the meaning set forth in Section 10.3.4 (*Cooperation*)

1.151 "**Notice of Arbitration**" has the meaning set forth in Section 15.1.1 (*Dispute Resolution*).

1.152 "**Notice of Dispute**" has the meaning set forth in Section 15.1.1 (*Dispute Resolution*).

1.153 "**OFAC**" means the Office of Foreign Assets Control of the United States Department of the Treasury or any successor agency thereto.

1.154 "**Open Budget Study**" has the meaning set forth in Section 5.2 (*Initial Global Development Plan*).

1.155 "**Operational Team**" has the meaning set forth in Section 3.5.3 (*Operational Teams*).

1.156 "**Other Active Ingredient**" means any active pharmaceutical or biological ingredient that is not a Licensed Compound.

1.157 "**Other Components**" means any Other Active Ingredients, diagnostic tools, biomarkers or devices.

1.158 "**Other Covered Party**" means any political party or party official, or any candidate for political office.

1.159 "**Party**" has the meaning set forth in the Preamble.

1.160 "**Party Vote**" has the meaning set forth in Section 3.7.1 (*General Decision-Making Process*).

1.161 "**Patent Challenge**" means an official action, suit, or proceeding challenging the validity, patentability, scope, priority, construction, inventorship, enforceability of an issued Patent Right, in an administrative or judicial forum independent of a claim of infringement. For clarity, a Patent Challenge shall not include (a) any claims (*e.g.*, a counterclaim in an invalidity proceeding) associated with an infringement action under Section 10.3 (*Enforcement Against Third Party Infringement or Misappropriation*) or Section 10.5 (*Third Party Infringement Claims*), or (b) any action filed in a good-faith effort to (i) reinforce the patentability, validity or enforceability of such Patent Right; or (ii) expand the claim scope of such Patent Right with respect to Licensed Compounds or Licensed Products.

1.162 "**Patent Prosecution**" means, with respect to a Patent Right, all activities directed to (a) preparing, filing, and prosecuting applications (of all types) for such Patent Right through issuance, as well as all post-issuance activities not involving a Third Party challenger, including for example ex parte re-examinations, reissues and appeals and other similar proceedings with respect to such Patent Right (but excluding the defense of challenges to such Patent Right as a counterclaim in an infringement proceeding) with respect to the particular Patent Right, and any appeals therefrom, and actions to obtain patent term extensions and supplementary protection certificates with respect to such Patent Right and the like, (b) maintaining any Patent Right, and (c) deciding whether to abandon or maintain any Patent Right. For clarification, "Patent Prosecution" will not include any other enforcement actions taken with respect to a Patent Right.

1.163 "**Patent Rights**" means (a) all patents and patent applications in any country or jurisdiction, including provisional applications, (b) all patent applications filed either from such patents or patent applications or from an application claiming priority from any of these or any substitution, divisional, continuation, continuation-in-part, reissue, renewal, registration, confirmation or the

like of any such patent or patent application, and (c) any extensions and restorations by any existing or future extension or restoration mechanism, including revalidations, reissues, re-examinations or extensions, including any supplemental protection certificates of the foregoing patents or patent applications.

1.164 "**Person**" means any corporation, limited or general partnership, limited liability company, joint venture, trust, unincorporated association, governmental body, authority, bureau, or agency, or any other entity or body, or an individual.

1.165 "**Pharmacovigilance Agreement**" means an agreement regarding receipt, investigation, and reporting of adverse events, and any other information related to the safety of the Licensed Products in the Territory.

1.166 "**Phase 3 Clinical Trial**" means, as to a pharmaceutical or biologic product, a clinical trial in humans performed to gain evidence with statistical significance of the efficacy of such product in a target population, and to obtain expanded evidence of safety for such product that is needed to evaluate the overall benefit-risk relationship of such product, to form the basis for approval of a MAA by a Regulatory Authority and to provide an adequate basis for physician labeling, in a manner that is generally consistent with 21 C.F.R. § 312.21(c), as amended (or its successor regulation), or, with respect to any other country or jurisdiction, the equivalent of such a clinical trial in such other country or jurisdiction.

1.167 "**PHSA**" means the United States Public Health Service Act, as amended from time-to-time, together with any rules, regulations, and requirements promulgated thereunder (including all additions, supplements, extensions, and modifications thereto).

1.168 "**Positive Data Readout**" means, with respect to the Global Phase 3 REACH Study, [***].

1.169 "**Professional Requirements**" means (a) the codes and standards of the European Accreditation Council for Continuing Medical Education (EACCME) and the European Federation of Pharmaceutical Industries and Associations (EFPIA), (b) the codes of the Prescription Medicines Code of Practice Authority (PMCPA) and the Association of the British Pharmaceutical Industry (ABPI), (c) FDA's regulations, guidance, and enforcement letters concerning the advertising of prescription drug products, (d) the American Medical Association's Guidelines on Gifts to Physicians from Industry, (e) the Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support of Continuing Medical Education, (f) the Pharmaceutical Supply Chain Initiative (PSCI) and Pharmaceutical Industry Principles for Responsible Supply Chain Management, (g) the Code on Interactions with Healthcare Professionals promulgated by the Pharmaceutical Research and Manufacturers of America (PhRMA Code), (h) the Department of Health and Human Services Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers (OIG Compliance Guidance), and (i) all other accepted national and international pharmaceutical industry codes of practice in and for the relevant countries in the Territory, as any of the foregoing may be amended from time-to-time.

1.170 "**Publication**" has the meaning set forth in Section 12.5.1(a) (*Publications under the Global Development Plan*).

1.171 "**Publishing Party**" has the meaning set forth in Section 12.5.1(c) (*Review Process and Other Limitations*).

1.172 "**Receiving Party**" has the meaning set forth in Section 12.1.1 (*Duty of Confidence*).

1.173 "**Region**" means any of the Asian Region, the European Region, the Latin American Region, or the ROW Region.

1.174 "**Regulatory Approval**" means, with respect to a particular country or other regulatory jurisdiction, any approval of an MAA or other approval, product, or establishment license, registration, or authorization of any Regulatory Authority necessary for the marketing and sale of a pharmaceutical, diagnostic, or biologic product in such country or other regulatory jurisdiction, including, as applicable, the approvals by the applicable Regulatory Authority of any expansion or modification of the label, and excluding, in each case, Reimbursement Approval.

1.175 "**Regulatory Authority**" means, in a particular country or jurisdiction, any applicable Governmental Authority involved in granting Regulatory Approval in such country or jurisdiction, including (a) in the U.S., the FDA and any other applicable Governmental Authority in the U.S. having jurisdiction over any pharmaceutical, diagnostic, or biologic product, (b) in the E.U., the EMA and any other applicable Governmental Authority in the E.U. having jurisdiction over any pharmaceutical, diagnostic, or biologic product, (c) in Japan, the Ministry of Health, Labor and Welfare of Japan ("**MHLW**") or any successor agency thereto having jurisdiction over any pharmaceutical, diagnostic, or biologic product and (d) in other countries, other analogous Governmental Authorities having jurisdiction over any pharmaceutical, diagnostic, or biologic product.

1.176 "**Regulatory Exclusivity**" means, with respect to a Licensed Product in a country in the Sanofi Territory, the period of time during which any data exclusivity rights, market exclusivity rights, or other exclusive right, other than a Patent Right, granted, conferred or afforded by any Regulatory Authority or otherwise under Applicable Law with respect to such Licensed Product, which either: (a) confers the exclusive legal right by a Regulatory Authority (or a Party or its Affiliate or Sublicensee is otherwise entitled to the exclusive legal right by operation of Applicable Law) in such country to market and sell such Licensed Product, and such right precludes a Third Party from making such Licensed Product available for purchase for any indication; or (b) prevents a Third Party from referencing or relying upon in any way the data and information submitted by a Party or its Affiliate or Sublicensee to the relevant Regulatory Authority in such country for purposes of obtaining Regulatory Approval, to support the Regulatory Approval or marketing of any product by such Third Party in such country, or if such data and information is referenced, or relied upon to support a Regulatory Approval granted to a Third Party in such country, prevents the product from being placed on the market for any indication.

1.177 "**Regulatory Milestone Event**" has the meaning set forth in Section 9.2.1 (*Regulatory Milestones*).

1.178 "**Regulatory Milestone Payment**" has the meaning set forth in Section 9.2.1 (*Regulatory Milestones*).

1.179 "**Regulatory Responsibility Transfer Date**" has the meaning set forth in Section 6.1 (*Regulatory Responsible Party*).

1.180 "**Regulatory Responsible Party**" means the Party designated under Section 6.1 (*Regulatory Responsible Party*).

1.181 "**Regulatory Submission**" means any regulatory registration, application, authorization and approval and any other submission with any Regulatory Authority (including drug master files) in

support of the Research, Development, Manufacture, Commercialization, or other Exploitation of a pharmaceutical, diagnostic, or biologic product (including to obtain, support, or maintain Regulatory Approval from that Regulatory Authority), and all written or electronic correspondence or communications with or from the relevant Regulatory Authority, as well as minutes of any material meetings, telephone conferences, or discussions with the relevant Regulatory Authority. Regulatory Submissions include all INDs, MAAs, and other applications for Regulatory Approval and their equivalents and all documents referenced in the complete regulatory chronology for each of the foregoing.

1.182 "**Reimbursement Approval**" means any approval, agreement, determination, or other decision by the applicable Governmental Authority in a given country that establishes prices charged to end-users for pharmaceutical, diagnostic, or biologic products at which such pharmaceutical, diagnostic, or biologic products will be reimbursed by the Regulatory Authorities or other applicable Governmental Authorities in such country.

1.183 "**Research**" means any pre-clinical research activities (including target validation, drug discovery, identification or synthesis) with respect to a given target, pharmaceutical product, biological product, or active pharmaceutical or biological ingredient with respect to the foregoing. "**Researching**," and "**Researched**" will be construed accordingly.

1.184 "**Residual Knowledge**" means intangible Know-How relating to the activities of the Parties with respect to the Research, Development, Manufacture, Commercialization or other Exploitation of Licensed Compounds or Licensed Products in the Field in the Territory as and to the extent set forth in this Agreement that is retained in the unaided memories of any employees or contractors of a Party or any of its Affiliates or Sublicensees who had access to such Know-How under this Agreement. For the purposes of this definition, any information intentionally memorized is not deemed to be retained in the unaided memory of a Person.

1.185 "**Restricted Party**" means any individual or entity on one or more of the Restricted Party Lists.

1.186 "**Restricted Party List**" means the list of sanctioned entities maintained by the United Nations; the Specially Designated Nationals and Blocked Persons List, the Foreign Sanctions Evaders List and the Sectoral Sanctions Identifications List, all administered by OFAC; the U.S. Denied Persons List, the U.S. Entity List, and the U.S. Unverified List, all administered by the U.S. Department of Commerce; and the entities subject to restrictive measures and the consolidated list of Persons, Groups, and Entities Subject to E.U. Financial Sanctions, as implemented by the E.U. Common Foreign & Security Policy.

1.187 "**Reversion Notice**" has the meaning set forth in Section 14.8.1 (*Reversion*).

1.188 "**Reversion Product**" has the meaning set forth in Section 14.8.1 (*Reversion*).

1.189 "**Review Period**" has the meaning set forth in Section 12.5.1(c) (*Review Process and Other Limitations*).

1.190 "**ROFN Exercise Notice**" has the meaning set forth in Section 2.8 (*Right of First Negotiation*).

1.191 "**ROFN Negotiation Period**" has the meaning set forth in Section 2.8 (*Right of First Negotiation*).

1.192 "**ROFN Notice**" has the meaning set forth in Section 2.8 (*Right of First Negotiation*).

1.193 "**ROW Region**" means all countries and territories within the Sanofi Territory that are not included in the Sanofi Major Countries, Asian Region, Latin American Region, or European Region.

1.194 "**Royalties**" has the meaning set forth in Section 9.3.1 (*Royalty Payments*).

1.195 "**Royalty Bearing Patent**" means, on a Licensed Product-by-Licensed Product and country-by-country basis, [***].

1.196 "**Royalty Payment**" has the meaning set forth in Section 9.3.1 (*Royalty Payments*).

1.197 "**Royalty Rates**" has the meaning set forth in Section 9.3.1 (*Royalty Payments*).

1.198 "**Royalty Report**" has the meaning set forth in Section 9.3.3(a) (*Royalty Report*).

1.199 "**Royalty Term**" means, on a Licensed Product-by-Licensed Product and country-by-country basis, the period of time commencing upon First Commercial Sale of such Licensed Product in such country and ending on the latest to occur of: (a) [***] after First Commercial Sale of such Licensed Product in such country, (b) the date on which the sale of such Licensed Product even without the licenses granted hereunder would no longer infringe a Royalty Bearing Patent, and (c) loss of Regulatory Exclusivity of such Licensed Product in such country.

1.200 "**Sales Milestone Event**" has the meaning set forth in Section 9.2.2 (*Sales Milestones*).

1.201 "**Sales Milestone Payment**" has the meaning set forth in Section 9.2.2 (*Sales Milestones*).

1.202 "**Sanofi**" has the meaning set forth in the Preamble.

1.203 "**Sanofi Background Technology**" has the meaning set forth in Section 1.217 (*Sanofi Technology*).

1.204 "**Sanofi Collaboration Technology**" has the meaning set forth in Section 1.217 (*Sanofi Technology*).

1.205 "**Sanofi Development Cost Share Notice**" has the meaning set forth in Section 5.7.1 (*Eligible Global Development Costs*).

1.206 "**Sanofi Indemnitees**" has the meaning set forth in Section 13.1(*Indemnification by Fulcrum*).

1.207 "**Sanofi Independent Development Activities**" has the meaning set forth in Section 5.2 (*Initial Global Development Plan*).

1.208 "**Sanofi Independent Development Plan**" has the meaning set forth in Section 5.5 (*Sanofi Independent Development Plan*).

1.209 "**Sanofi Independent Development Program**" means the program of Development activities conducted under the Sanofi Independent Development Plan, which, for clarity, will exclude any Development activities conducted under the Global Development Program or the Fulcrum Independent Development Program.

1.210 "**Sanofi Know-How**" means, subject to Section 5.3.1(c)(iii) (*Additional Activities under Global Development Plan*), all Collaboration Know-How (excluding Sanofi's interest in Joint

Collaboration Know-How) that is (a) Controlled by Sanofi or any of its Affiliates as of the Effective Date or during the Term and (b) necessary or reasonably useful to Exploit a Licensed Compound or Licensed Product in the Field in the Fulcrum Territory.

1.211 "**Sanofi Major Country**" means each of [***].

1.212 "**Sanofi Manufacturing Technology**" means any Patents Rights or Know-How Controlled by Sanofi or its Affiliates that directly Cover (in the case of Patent Rights) or directly relate to (in the case of Know-How) Manufacturing.

1.213 "**Sanofi Patent Rights**" means all Collaboration Patent Rights (excluding Sanofi's interest in Joint Collaboration Patent Rights) that are (a) Controlled by Sanofi or any of its Affiliates as of the Effective Date or during the Term and (b) necessary or reasonably useful (or, with respect to patent applications, would be necessary or reasonably useful if such patent applications were to issue as patents) to Exploit a Licensed Compound or Licensed Product in the Field in the Fulcrum Territory.

1.214 "**Sanofi Product Trademarks**" has the meaning set forth in Section 10.11.1(a) (*Ownership of Sanofi Product Trademarks*).

1.215 "**Sanofi Prosecuted Patent Rights**" has the meaning set forth in Section 10.2.2(a) (*Right to Prosecute*).

1.216 "**Sanofi Reversion Technology**" has the meaning set forth in Section 14.8.1(a) (*Reversion License*).

1.217 "**Sanofi Technology**" means (a) Background Technology Controlled by Sanofi or its Affiliates that (i) Covers or is incorporated in a Licensed Product that is or was in clinical Development under the Global Development Plan in the form and manner in which such Licensed Product is or was in clinical Development under the Global Development Plan, or (ii) is actually used by Sanofi or its Affiliates or Sublicensees in the Commercialization of a Licensed Product in the Sanofi Territory (collectively ((a)(i) and (a)(ii)), the "**Sanofi Background Technology**"), (b) Collaboration Patent Rights and Collaboration Know-How solely conceived, discovered, developed, invented or otherwise made by Sanofi or its Affiliates, licensees', Sublicensees', or subcontractors' employees, agents, or independent contractors, or any Persons contractually required to assign or license such Patent Rights or Know-How to Sanofi or any Affiliate of Sanofi in the performance of activities under this Agreement ("**Sanofi Collaboration Technology**"), and (c) Sanofi's interest in the Joint Collaboration Technology.

1.218 "**Sanofi Territory**" means worldwide, except for the Fulcrum Territory.

1.219 "**Sanofi Territory Manufacturing Handover Date**" has the meaning set forth in Section 8.1.2 (*Sanofi Manufacturing*).

1.220 "**Securitization Transaction**" has the meaning set forth in Section 16.1 (*Assignment*).

1.221 "**Shelving Event**" has the meaning set forth in Section 14.5.1 (*Shelving Event*).

1.222 "**Step-In Activities**" has the meaning set forth in Section 5.4 (*Sanofi Step-In Right under Global Development Plan*).

1.223 "**Strategic Business Rationale**" means, with respect to a Party, a reasonable business determination that not refraining to act would reasonably be expected to improve the competitive or financial position of, or otherwise increase the profitability or value of, a Licensed Product by a degree that is greater than the potential adverse impact on such Licensed Product if such action is taken by such Party.

1.224 "**Subcommittee**" has the meaning set forth in Section 3.5.1 (*Formation; Authority*).

1.225 "**Sublicensee**" means, with respect to a Party, any Third Party to which such Party or its Affiliate grants a sublicense under any of the rights licensed to such Party pursuant to Article 2 (*Licenses*), but excluding any Third Party to the extent such Third Party is acting as a Distributor or, with respect to such Party or its Affiliate, as applicable, a contract manufacturing organization or contract research organization carrying out subcontracted activities on behalf of such Party or its Affiliate.

1.226 "**Supply Agreement**" has the meaning set forth in Section 8.2 (*Supply Agreement*).

1.227 "**Tax**" or "**Taxes**" means any present or future taxes, levies, imposts, duties, charges, assessments or fees of any nature (including any interest thereon), including value add, sales, excise or similar taxes.

1.228 "**Technology Transfer**" has the meaning set forth in Section 4.2 (*Continuing Technology Transfer*).

1.229 "**Term**" has the meaning set forth in Section 14.1 (*Term*).

1.230 "**Terminated Product**" means: (a) in the case of the termination of this Agreement with respect to one or more Licensed Products pursuant to Section 14.3 (*Termination by Sanofi for Convenience*) or Section 14.4 (*Termination by Sanofi for Safety*) such Licensed Products that are the subject of such termination; (b) in the case of termination of this Agreement with respect to one or more countries or Regions pursuant to Section 14.3 (*Termination by Sanofi for Convenience*), all Licensed Products in such Terminated Regions; or (c) in the case of the termination of this Agreement in its entirety pursuant to Article 14 (*Term and Termination*), all Licensed Products in all countries in the Territory.

1.231 "**Terminated Region**" has the meaning set forth in Section 14.3 (*Termination by Sanofi for Convenience*).

1.232 "**Territory**" means (a) the Sanofi Territory, with respect to Sanofi, (b) the Fulcrum Territory, with respect to Fulcrum, and (c) collectively, worldwide.

1.233 "**Third Party**" means any Person other than a Party or its Affiliates.

1.234 "**Third Party Claims**" has the meaning set forth in Section 13.1 (*Indemnification by Fulcrum*).

1.235 "**Third Party Infringement**" has the meaning set forth in Section 10.5.1 (*Notification*).

1.236 "**Third Party Patent Challenge**" has the meaning set forth in Section 10.4 (*Defense of Third Party Patent Challenges*).

1.237 "**Third Party Payments**" has the meaning set forth in Section 9.3.2(c)(i) (*Royalty Stacking – By Sanofi*).

1.238 "**Trademark**" means any word, name, symbol, color, shape, designation or any combination thereof, including any trademark, service mark, trade name, brand name, sub-brand name, trade dress, product configuration, program name, delivery form name, certification mark, collective mark, logo, tagline, slogan, design or business symbol, that functions as an identifier of source or origin, whether or not registered and all statutory and common law rights therein and all registrations and applications therefor, together with all goodwill associated with, or symbolized by, any of the foregoing.

1.239 "**Transition Services Agreement**" has the meaning set forth in Section 14.8.6 (*Transition Services Agreement*).

1.240 "**Upfront Payment**" has the meaning set forth in Section 9.1 (*Upfront Payment*).

1.241 "**U.S.**" means the United States of America (including all possessions and territories thereof, including Puerto Rico).

1.242 "**U.S. Dollars**" or "**$**" means the legal tender of the U.S.

1.243 "**Unified Patent Court**" means the court established by the EU under the Unified Patent Court Agreement of 19 February 2013 (2013/C 175/01) (OJEU 20.6.2013, C 175/1).

1.244 "**Valid Claim**" means on a Licensed Product-by-Licensed Product and country-by-country basis, (a) a claim of an issued and unexpired Patent Right within the Fulcrum Patent Rights, and that has not been held unenforceable, unpatentable or invalid by a decision of a court or national or regional patent office or other Governmental Authority of competent jurisdiction in a final judgement (or judgement from which no appeal was taken within the allowable time period); or which has not been admitted to be invalid or unenforceable through abandonment, reissue, disclaimer or otherwise, or (b) a pending patent application within the Fulcrum Patent Rights, which was filed and continues to be prosecuted in good faith, and which has not, in the relevant country, been cancelled, withdrawn, or abandoned. Notwithstanding the foregoing, on a country-by-country basis, a patent application pending for more than [***] from the earliest effective priority date to which such claim is entitled will not be considered to have any Valid Claim for purposes of this Agreement unless and until a patent that meets the criteria set forth in clause (a) in the preceding sentence issues with respect to such application at issue.

1.245 "**Withheld Amount**" has the meaning set forth in Section 9.11.2 (*Withholding Tax*).

ARTICLE 2
LICENSES

.1 License Grant to Sanofi. Subject to the terms of this Agreement, Fulcrum hereby grants to Sanofi an exclusive, non-transferable (except in accordance with Section 16.1 (*Assignment*)), [***] with the right to grant sublicenses through multiple tiers, solely in accordance with Section 2.3.1 (*Rights to Grant Sublicenses*), under the Fulcrum Technology to:

2.1.1 Research, Develop, and Manufacture the Licensed Compounds and Licensed Products in the Field in the Territory (including, for clarity, the Fulcrum Territory) solely for the

performance of activities in the Global Development Plan allocated to Sanofi or the Sanofi Independent Development Plan;

2.1.2 Manufacture the Licensed Compounds and Licensed Products in the Territory (including, for clarity, the Fulcrum Territory) solely for Commercialization of such Licensed Compound or Licensed Product in the Field in the Sanofi Territory;

2.1.3 Commercialize and otherwise Exploit (other than Research, Develop, and Manufacture) the Licensed Compounds and Licensed Products in the Field in the Sanofi Territory; and

2.1.4 Subject to Section 2.2 (*License Grants to Fulcrum*), Research, Develop, and Manufacture the Licensed Compounds and Licensed Products in the Field in the Sanofi Territory.

The Parties agree and acknowledge that Fulcrum does not Control the GSK Patent Rights for the purposes of Exploiting the Licensed Compounds as described under clause (b) or (c) of Section 1.129 (*Definition of Licensed Compound*) or Licensed Products containing such Licensed Compounds and that no such rights are granted to Sanofi under this Section 2.1 (*License Grant to Sanofi*) or otherwise under this Agreement.

2.2 License Grants to Fulcrum. Subject to the terms of this Agreement, Sanofi hereby grants to Fulcrum:

2.2.1 a non-exclusive, non-transferable (except in accordance with Section 16.1 (*Assignment*)), royalty-free license, with the right to grant sublicenses through multiple tiers solely in accordance with Section 2.3.1 (*Rights to Grant Sublicenses*) under the Fulcrum Technology licensed by Fulcrum to Sanofi under Section 2.1 (*License Grant to Sanofi*) and under the Sanofi Technology that is not Sanofi Manufacturing Technology to the extent necessary to Manufacture the Licensed Compounds and Licensed Products in the Field in the Territory solely for Commercialization of such Licensed Compound or Licensed Product in the Field in the Sanofi Territory under the Supply Agreement;

2.2.2 an exclusive (except with respect to Sanofi in order for Sanofi to exercise any rights expressly granted to Sanofi under this Agreement), non-transferable (except in accordance with Section 16.1 (*Assignment*)), royalty-free license, with the right to grant sublicenses through multiple tiers solely in accordance with Section 2.3.1 (*Rights to Grant Sublicenses*) under the Fulcrum Technology licensed by Fulcrum to Sanofi under Section 2.1 (*License Grant to Sanofi*) solely to:

(a) Research, Develop and Manufacture the Licensed Compounds and Licensed Products in the Field in the Territory (including, for clarity, the Sanofi Territory) solely for the performance of activities in the Global Development Plan allocated to Fulcrum or the Fulcrum Independent Development Plan, and

(b) Manufacture the Licensed Compounds and Licensed Products in the Territory (including, for clarity, the Sanofi Territory) solely for Commercialization of such Licensed Compound or Licensed Product in the Field in the Fulcrum Territory; and

2.2.3 subject to Section 2.11 (*Licensed Sanofi Technology*), an exclusive (except with respect to Sanofi in order for Sanofi to exercise any rights expressly granted to Sanofi under this Agreement), non-transferable (except in accordance with Section 16.1 (*Assignment*)),

[***] license, with the right to grant sublicenses through multiple tiers solely in accordance with Section 2.3.1 (*Rights to Grant Sublicenses*) under the Licensed Sanofi Technology, solely to:

(a) Research, Develop and Manufacture the Licensed Compounds and Licensed Products in the Field in the Territory (including, for clarity, the Sanofi Territory) solely for the performance of activities in the Global Development Plan allocated to Fulcrum or the Fulcrum Independent Development Plan,

(b) Commercialize and otherwise Exploit (other than Research, Develop and Manufacture) the Licensed Compounds and Licensed Products in the Field in the Fulcrum Territory, and

(c) Manufacture the Licensed Compounds and Licensed Products in the Territory (including, for clarity, the Sanofi Territory) solely for Commercialization of such Licensed Compound or Licensed Product in the Field in the Fulcrum Territory.

2.3 Sublicensing and Subcontracting Terms.

2.3.1 **Rights to Grant Sublicenses**. Subject to the terms of this Agreement, each Party will have the right to grant sublicenses of the rights granted under Section 2.1 (*License Grant to Sanofi*) and Section 2.2 (*License Grants to Fulcrum*), as applicable, to its Affiliates or to any Third Party.

2.3.2 **Effects of Termination on Sanofi Sublicenses to a Third Party**. If this Agreement is terminated for any reason, any sublicense granted hereunder by Sanofi to a Third Party will, at the Sublicensee's request within [***] of such termination, survive such termination; *provided* that (a) the relevant Sublicensee is not in breach of any of its obligations under such sublicense, (b) Fulcrum is not required to assume any obligations or liabilities (contingent or otherwise) not set forth in this Agreement, (c) such Sublicensee agrees in writing to comply with all of the terms and conditions of this Agreement to the extent applicable to the rights originally sublicensed to it by Sanofi, and (d) such Sublicensee agrees to assume all of Sanofi's financial obligations under this Agreement to the extent applicable to the rights sublicensed to it by Sanofi.

2.3.3 **Right to Subcontract**. Each Party may engage one or more Third Party subcontractors to perform services in furtherance of the performance of its obligations or exercise of its rights under this Agreement; *provided* that (a) neither Party will engage any such Third Party that has been Debarred/Excluded; and (b) no engagement of any such Third Party subcontractors will relieve the engaging Party of its obligations under this Agreement or any liability hereunder.

2.3.4 **Sublicense and Subcontract Agreements**. Each sublicense granted pursuant to this Section 2.3 (*Sublicensing and Subcontracting Terms*) and each agreement pursuant to which each Party engages any Third Party subcontractor will (a) be subject and subordinate to this Agreement, (b) be consistent with the terms of this Agreement, (c) include obligations of confidentiality and non-use applicable to the Confidential Information of the other Party that are at least as stringent as those set forth in Article 12 (*Confidentiality*), and (d) include terms that are consistent with the intellectual property provisions set forth in this Agreement, unless the Parties mutually agree otherwise in writing. Sanofi will provide Fulcrum with a copy of any executed sublicense agreement with a Third Party (but,

for clarity, not any agreement that is solely for the engagement of a Third Party subcontractor and entered into by Sanofi pursuant to Section 2.3.3 (*Right to Subcontract*)), which copy may be redacted as necessary to protect confidential information that is not necessary to confirm compliance with this Agreement, as soon as reasonably practicable after execution of such sublicense agreement.

2.3.5 **Responsibility for Sublicensees and Subcontractors**. Notwithstanding any sublicense, the sublicensing or subcontracting Party will remain primarily liable to the other Party for the performance of all of its obligations under, and such Party's compliance with all provisions of, this Agreement. Each Party agrees that it will be fully responsible and liable for any breach of the terms of this Agreement by any of its Sublicensees or subcontractors to the same extent as if such Party itself has committed any such breach.

2.4 No Other Rights and Retained Rights. Nothing in this Agreement will be interpreted to grant a Party any rights under any intellectual property rights owned or Controlled by the other Party, including Fulcrum Technology and Sanofi Technology (including any Sanofi Reversion Technology), in each case, that are not expressly granted herein, whether by implication, estoppel, or otherwise. Any rights not expressly granted to a Party by the other Party under this Agreement are hereby retained by such other Party. Neither Fulcrum nor Sanofi will, or will grant any Affiliate or Third Party rights to, Research, Develop, Manufacture, Commercialize or otherwise Exploit a Licensed Compound or Licensed Product except as permitted under this Agreement which, for clarity, shall mean that neither Fulcrum nor Sanofi will, or will grant any Affiliate or Third Party rights to, Research or Develop except as contemplated by the Global Development Plan or, as applicable, the Sanofi Independent Development Plan or the Fulcrum Independent Development Plan.

2.5 Existing Third Party IP Agreements.

2.5.1 **Amendments to Existing Third Party IP Agreements**. During the Term, Fulcrum will promptly furnish Sanofi with copies of any amendment to any Existing Third Party IP Agreement to the extent related to any of the rights sublicensed to Sanofi hereunder, from which copies Fulcrum may redact information that is not relevant to the rights sublicensed to Sanofi pursuant to the applicable Existing Third Party IP Agreement. Fulcrum will not, without Sanofi's prior consent, terminate any Existing Third Party IP Agreement or execute any amendment to any Existing Third Party IP Agreement or otherwise modify any Existing Third Party IP Agreement, in each case, to the extent that doing so would (i) conflict with or adversely affect the rights granted to Sanofi under this Agreement, or (ii) conflict with or adversely affect Fulcrum's or Sanofi's ability to fulfill its obligations under this Agreement.

2.5.2 **Breach of Existing Third Party IP Agreements**. In the event of any written notice of breach by Fulcrum given under the provisions of any Existing Third Party IP Agreement, Fulcrum shall immediately notify Sanofi in writing and if Fulcrum fails to cure such breach and the breach (a) is not due to an act or omission of Sanofi, its Affiliates or Sublicensees and (b) remains outstanding and undisputed, Sanofi shall have the right, but not the obligation, to cure such breach on behalf of Fulcrum or its Affiliates, as applicable, and [***]. In the event Fulcrum provides written notice of any breach by the counterparty to the applicable Existing Third Party IP Agreement, Fulcrum shall immediately notify Sanofi in writing, and Fulcrum shall use Commercially Reasonable Efforts to enforce such Existing Third Party IP Agreement.

2.5.3 **Termination of Existing Third Party IP Agreements**. Without limiting the foregoing, in the events of (a) early termination of any Existing Third Party IP Agreement during the Term, and (b) Sanofi acquiring a direct license from such counterparty under the rights formerly sublicensed to Sanofi by Fulcrum under such Existing Third Party IP Agreement, [***].

2.5.4 **Existing Third Party IP Notices**. In the event Fulcrum receives a written notice under an Existing Third Party IP Agreement that is relevant to any of the rights sublicensed to Sanofi under this Agreement (including, without limitation, notice of assignment of the GSK Side Letter), Fulcrum will promptly provide to Sanofi a copy of such notice.

2.6 New Third Party IP Agreements.

2.6.1 **Core Third Party IP**.

(a) Upon written notice to Sanofi, Fulcrum will have the first right, at its sole cost and expense, to obtain any Patent Rights or Know-How (whether through acquisition or a license) that it reasonably believes are Core Third Party IP. Fulcrum shall include within such written notice a description of such Patent Rights and Know-How, and shall have a period of [***] after provision of such written notice (the "**Fulcrum Negotiation Period**") to obtain rights to such Core Third Party IP in accordance with the following clause (c); *provided, however*, that, if Fulcrum is engaged in *bona fide* discussions with the relevant Third Party licensor at the expiration of the Fulcrum Negotiation Period, then Fulcrum may notify Sanofi and the Fulcrum Negotiation Period will be extended for an additional [***] (or such longer period as mutually agreed by the Parties).

(b) Fulcrum will (i) use reasonable efforts to ensure that any rights to Core Third Party IP are (A) consistent in scope with the scope of Fulcrum's license grants to Sanofi under Section 2.1.1 (*License Grant to Sanofi*), Section 2.1.2 (*License Grant to Sanofi*), and Section 2.1.3 (*License Grant to Sanofi*) in the Field in the Territory and (B) fully licensable or sublicensable to Sanofi and (ii) as between the Parties, be responsible for [***] of all payments arising in connection with Fulcrum's acquisition of or license under such Core Third Party IP, including any payments arising as a result of Sanofi's exercise of its license or sublicense under such Core Third Party IP pursuant to this Agreement. If Fulcrum obtains rights to any Core Third Party IP that are not (A) consistent in scope with the scope of Fulcrum's license grants to Sanofi under Section 2.1.1 (*License Grant to Sanofi*), Section 2.1.2 (*License Grant to Sanofi*), and Section 2.1.3 (*License Grant to Sanofi*) in the Field in the Territory or (B) fully licensable or sublicensable to Sanofi, then Fulcrum will ensure that the scope of such rights to such Core Third Party IP does not prevent Sanofi from obtaining rights directly from the applicable Third Party that are consistent in scope with the scope of Fulcrum's license grants to Sanofi under Section 2.1.1 (*License Grant to Sanofi*), Section 2.1.2 (*License Grant to Sanofi*), and Section 2.1.3 (*License Grant to Sanofi*) in the Field in the Territory.

(c) If Fulcrum does not acquire or obtain rights to such Core Third Party IP within the Fulcrum Negotiation Period or if Fulcrum obtains rights to such Core Third Party IP that do not prevent Sanofi from obtaining rights to such Core Third Party IP directly from the applicable Third Party, then, in either case, Sanofi will have the right, at its sole cost and expense (subject to Section 9.3.2(c)(i) (*Royalty Stacking*

– *By Sanofi*)), to obtain a license to such Core Third Party IP for Exploitation of Licensed Compounds and Licensed Products in the Field in the Territory; *provided* that such license is, with respect to the Licensed Compounds and Licensed Products, no broader in scope than the scope of Fulcrum's license grants to Sanofi under Section 2.1.1 (*License Grant to Sanofi*), Section 2.1.2 (*License Grant to Sanofi*), and Section 2.1.3 (*License Grant to Sanofi*). For clarity, Sanofi will not be restricted from obtaining rights broader than the scope of such license grants with respect to the Exploitation of any compounds or products other than the Licensed Compounds and Licensed Products.

2.6.2 **New Collaboration In-Licenses**. Without limiting the rights and obligations of the Parties with respect to Core Third Party IP as set out in Section 2.6.1 (*Core Third Party IP*):

(a) Upon execution of any agreement by a Party or its Affiliates with a Third Party for any Patent Rights or Know-How that are necessary or actually used by either Party to Develop, Manufacture or Commercialize a Licensed Compound or Licensed Product in the Field in the Territory (any such agreement, including any such agreement for Core Third Party IP, a "**New Third Party IP Agreement**" and such Patent Rights or Know-How, "**New Third Party IP Rights**"), and *provided* that such New Third Party IP Rights are sublicensable under the New Third Party IP Agreement, the executing Party will notify the other Party in writing and will provide a copy of the New Third Party IP Agreement to such other Party, which may be redacted to exclude information not related to the sublicensed rights.

(b) Within [***] of delivery of notification of a New Third Party IP Agreement, the notified Party must let the notifying Party know in writing if it would like to receive a sublicense under such New Third Party IP Rights and if the notified Party so elects:

(i) such New Third Party IP Agreement shall be deemed to be a "**Collaboration In-License**" under this Agreement,

(ii) the New Third Party IP Rights licensed under such Collaboration In-License will be deemed to be "Controlled" under this Agreement (if the definition of "Control" is otherwise met) as Fulcrum Technology or deemed to be Licensed Sanofi Technology (as applicable) and licensed or sublicensed (as applicable) to the notified Party under the licenses granted in Section 2.1 (*License Grant to Sanofi*) or Section 2.2 (*License Grants to Fulcrum*), subject to the terms of this Agreement and the applicable New Third Party IP Agreement,

(iii) the notified Party will abide by the applicable terms of such New Third Party IP Agreement to the extent disclosed to it, and

(iv) unless otherwise agreed upon by the Parties in writing and, except as otherwise set forth with respect to Core Third Party IP in Section 2.6.1 (*Core Third Party IP*), (A) each Party will be responsible for all payments under such New Third Party IP Agreement that are specific to such Party's Territory (*e.g.*, running royalties resulting from net sales of products in the applicable Territory) or to activities under the Fulcrum Independent Development Plan (if such Party is Fulcrum) or to activities under the Sanofi Independent Development Plan (if such Party is Sanofi), and (B) the Parties will allocate any non-Territory specific upfront payments, milestone payments, or similar payments payable under such New Third Party IP Agreement as Eligible Global Development Costs to the extent allocable to the

Global Development Program and otherwise such payments will [***] by the Parties, in each case (A) and (B), subject to Section 9.3.2(c)(i) (*Royalty Stacking – By Sanofi*).

(c) In the event a Party does not elect to receive a sublicense under a New Third Party IP Agreement under Section 2.6.2(b) (*New Collaboration In-Licenses*), it will not receive any rights under such New Third Party IP Agreement or the New Third Party IP Rights subject to such Agreement and the Party who has executed the New Third Party IP Agreement will be, as between the Parties, solely responsible for [***] of the payments under such agreement, subject to Section 9.3.2(c)(i) (*Royalty Stacking – By Sanofi*).

2.7 Exclusivity.

2.7.1 **Exclusivity Obligations**. Subject to Section 2.7.2 (*Acquisition of a Competitive Product*) and Section 2.7.3 (*Change of Control*), and except as expressly permitted in respect of a Licensed Compound or a Licensed Product under this Agreement, during [***], Fulcrum and its Affiliates will not work independently or for or with any Third Party, or grant rights to any Third Party, (including the grant of any license to any Third Party) to [***] (a "**Competitive Product**") anywhere in the Territory.

2.7.2 **Acquisition of a Competitive Product**. Notwithstanding the provisions of Section 2.7.1 (*Exclusivity Obligations*), if Fulcrum or any of its Affiliates acquires rights to Research, Develop, Manufacture, Commercialize or otherwise Exploit a Competitive Product as the result of a merger, acquisition, or combination with or of a Third Party (where Fulcrum is not the acquired entity) other than a Change of Control of Fulcrum (each, an "**Acquisition Transaction**") and, on the date of the closing of such Acquisition Transaction, such Competitive Product is being Researched, Developed, Manufactured, Commercialized or otherwise Exploited, and such activities would, but for the provisions of this Section 2.7.2 (*Acquisition of a Competitive Product*), constitute a breach of Section 2.7.1 (*Exclusivity Obligations*), then Fulcrum or its Affiliate will, within [***] after the closing of such Acquisition Transaction notify Sanofi in writing of such acquisition and either:

(a) request that such Competitive Product be included in this Agreement on terms to be negotiated, in which case, the Parties will discuss the matter in good faith for a period of [***] (or such longer period as may be agreed by the Parties) and, if the Parties are unable to reach agreement on the terms on which such Competitive Product would be included hereunder within such period, then Fulcrum will elect to take the action specified in either Section 2.7.2(b) or Section 2.7.2(c) below; *provided* that the time periods specified in such clauses will be tolled for so long as the Parties are engaged in good faith discussion under this Section 2.7.2(a);

(b) notify Sanofi in writing that Fulcrum or its Affiliate will Divest its entire interest in and with respect to such Competitive Product, in which case, within [***] after the closing of the Acquisition Transaction, Fulcrum or its Affiliate will Divest its entire interest in and with respect to such Competitive Product; or

(c) notify Sanofi in writing that it is ceasing all such Research, Development, Manufacturing, Commercialization and Exploitation activities with respect to the Competitive Product, in which case, within [***] after Sanofi's receipt of such notice, Fulcrum and its Affiliates will cease all such activities.

During the discussion period under Section 2.7.2(a), prior to the time of Divestiture pursuant to Section 2.7.2(b), or prior to the termination of activities pursuant to Section 2.7.2(c), as applicable, Fulcrum and its Affiliates will (i) establish and enforce customary and commercially reasonable internal processes, policies, procedures and systems to segregate information relating to any such Competitive Product from any Confidential Information related to the Licensed Compounds or Licensed Products under this Agreement, (ii) not use, directly or indirectly, any Patent Rights, Know-How or Confidential Information relating to the Licensed Compound, the Licensed Product, or the Research, Development, Manufacturing, Commercialization or other Exploitation thereof in the Research, Development, Manufacturing, Commercialization or other Exploitation of such Competitive Product, and (iii) segregate all activities relating to the Competitive Product from the Research, Development, Manufacturing, Commercialization or other Exploitation of the Licensed Products under this Agreement, including ensuring that (A) no personnel involved in performing Research, Development, Manufacturing, Commercialization or other Exploitation activities with respect to such Competitive Product have access to plans or information relating to the Research, Development, Manufacturing, Commercialization or other Exploitation of the Licensed Products (except that senior management personnel may review and evaluate plans and information regarding the Research, Development, Manufacture, Commercialization and other Exploitation of the Licensed Products in connection with portfolio decision-making), and (B) no personnel involved in performing Research, Development, Manufacturing, Commercialization or other Exploitation activities with respect to the Licensed Products have access to plans or information relating to the Research, Development, Manufacture, Commercialization or other Exploitation of such Competitive Product (except that senior management personnel may review and evaluate plans and information regarding the Research, Development, Manufacture, Commercialization and other Exploitation of such Competitive Product in connection with portfolio decision-making). The procedures set forth in clauses (i) through (iii) above will be referred to as "**Firewall Procedures**" for the purposes of this Agreement. Fulcrum shall document the establishment of the Firewall Procedures by reasonable written records and provide such reasonable written records to Sanofi upon reasonable written request.

2.7.3 **Change of Control**. If there is a Change of Control involving Fulcrum (where Fulcrum is the acquired entity), then the obligations of Section 2.7.1 (*Exclusivity Obligations*) will not apply to any Competitive Product that is controlled by the relevant acquirer or its Affiliates that were not Affiliates of Fulcrum prior to the relevant Change of Control; *provided* that (a) Fulcrum, the acquirer and such Affiliates establish and enforce internal processes, policies, procedures, and systems to segregate information relating to any such Competitive Product from any Confidential Information related to the Licensed Compounds and Licensed Products that are at least as restrictive as the Firewall Procedures, (b) the acquirer and such Affiliates do not use, directly or indirectly, any Patent Rights, Know-How, or Confidential Information of such Party (including any Patent Rights, Know-How, or Confidential Information licensed or acquired from the other Party under this Agreement) to Exploit any such Competitive Product, and (c) Fulcrum and the acquirer use commercially reasonable efforts to segregate all activities relating to any such Competitive Product from the Research, Development, Manufacture, Commercialization or other Exploitation of the Licensed Compounds and Licensed Products, including ensuring that

no personnel who were employees or consultants of Fulcrum or its Affiliates at any time prior to or after the Change of Control conducts any activities to Research, Development, Manufacture, Commercialization other otherwise Exploit any such Competitive Product. Fulcrum shall document the establishment of the safeguards set forth in clauses (a) through (c) above by reasonable written records and provide such reasonable written records to Sanofi upon reasonable written request.

2.8 Right of First Negotiation. If Fulcrum or any of its Affiliates intend to enter into any confidential discussions with a Third Party with respect to the license, sale, assignment or other transfer or grant of rights (other than, in each case, the transfer or grant of solely subcontracting rights) to such Third Party to Research, Develop, or Commercialize any Licensed Compound or Licensed Product in the Field in the Fulcrum Territory, then, prior to entering into a non-disclosure agreement with such Third Party, Fulcrum shall provide to Sanofi written notice of the proposed scope of Research, Development or Commercialization rights that Fulcrum proposes to grant to such Third Party ("**ROFN Notice**"). Thereafter, Sanofi will have an exclusive right, exercisable no later than [***] after receipt of any such ROFN Notice from Fulcrum, to notify Fulcrum in writing as to whether Sanofi desires to negotiate for such rights to Research, Develop or Commercialize the Licensed Compounds or Licensed Products in the Fulcrum Territory (a "**ROFN Exercise Notice**"). If Sanofi provides a ROFN Exercise Notice to Fulcrum within such [***] period, then Sanofi will have a one-time right for [***] from the date of Fulcrum's receipt of the ROFN Notice (the "**ROFN Negotiation Period**") to require the Parties to exclusively negotiate in good faith the terms of a definitive agreement (or amendment to this Agreement) pursuant to which Fulcrum would grant to Sanofi the exclusive rights to Research, Develop or Commercialize the Licensed Compounds or Licensed Products in the Fulcrum Territory, and (b) upon Sanofi's request during the ROFN Negotiation Period, (i) Fulcrum will provide Sanofi with all information and documentation reasonably requested by Sanofi in Fulcrum's or its Affiliate's possession and Control relating to the Licensed Compounds or Licensed Products in the Fulcrum Territory and (ii) afford Sanofi and its representatives reasonable access during normal business hours to Fulcrum's personnel reasonably designated by Fulcrum to address Sanofi's inquiries. Neither Party will have any obligation to enter into any agreement or amendment to this Agreement granting rights to Sanofi to Research, Develop or Commercialize the Licensed Compounds or Licensed Products in the Fulcrum Territory. If the ROFN Negotiation Period expires before the Parties have entered into an agreement or amendment to this Agreement with respect to Sanofi's Research, Development or Commercialization of the Licensed Compounds or Licensed Products in the Fulcrum Territory, then Fulcrum will have no further obligation to negotiate with Sanofi with respect to any grant of such rights to Sanofi and, for a period of [***], will be free to negotiate and enter into an agreement with any Third Party with respect to a grant of rights to Research, Develop or Commercialize the Licensed Compounds or Licensed Products in the Fulcrum Territory, *provided* that (x) any transaction that is the subject of such negotiations and agreement with one or more Third Parties shall not exceed the scope of Development and Commercialization rights described in the applicable ROFN Notice; (y) Sanofi's exclusive negotiation rights under this Section 2.8 (*Right of First Negotiation*) shall remain in effect with respect to any negotiations by Fulcrum in respect of the Licensed Compounds or Licensed Products for transactions of a different scope; and (z) if Fulcrum or its Affiliates fail to enter into any such Third Party agreement during such [***] period, following expiration of such [***], Sanofi would again have the right of first negotiation for such rights in accordance with the provisions of this Section 2.8 (*Right of First Negotiation*). Notwithstanding anything to the contrary in this Section 2.8 (*Right of First Negotiation*), a Change of Control of Fulcrum or its Affiliates will not trigger Fulcrum's obligation to provide a ROFN Notice.

2.9 Change of Control of Fulcrum.

2.9.1 **Sale Process**. If Fulcrum or any of its Affiliates commences any process in connection with a Change of Control involving Fulcrum (where Fulcrum is the acquired entity), Fulcrum will (a) notify Sanofi of its intent to contact the applicable Third Party(ies) at least [***] prior to contacting any such Third Party, (b) allow Sanofi to participate in such process on terms at least as favorable as those terms offered to the other Third Parties, and (c) provide to Sanofi a copy of any data and information with respect to the Exploitation of the Licensed Compounds and Licensed Products Controlled and in the possession of Fulcrum but not previously provided to Sanofi.

2.9.2 **Unsolicited Offer**. If Fulcrum or any of its Affiliates receives an unsolicited offer from a Third Party for a Change of Control involving Fulcrum (where Fulcrum is the acquired entity), then Fulcrum will (a) provide to Sanofi written notice within [***] of receipt of such offer, (b) allow Sanofi to participate in any resulting process on terms at least as favorable as those terms offered to such Third Party offeror and (c) provide to Sanofi a copy of any data and information with respect to the Exploitation of the Licensed Compounds and Licensed Products not previously provided to Sanofi; *provided*, *however*, that if the board of directors of Fulcrum determines, in the exercise of its fiduciary duty, to exclusively negotiate with such Third Party, Fulcrum shall, unless not practicable or advisable in light of the Fulcrum board's fiduciary duties based on the advice of counsel, so notify Sanofi at least [***] prior to the commencement of the relevant exclusivity period and shall have no further obligations in respect of the foregoing clauses (b) and (c).

2.10 Residual Knowledge. Nothing in this Agreement shall be construed to restrict any Party from using Residual Knowledge for any purpose except to the extent such use of Residual Knowledge would infringe, misappropriate or otherwise violate an intellectual property right of the other Party, its Affiliates or Sublicensees, including infringement of a Patent Right or unlawful disclosure of a trade secret. Any use made by a Party of any such Residual Knowledge is on an "as is, where is" basis, with all faults and all representations and warranties disclaimed and at its sole risk.

2.11 Licensed Sanofi Technology.

2.11.1 **Non-Manufacturing Technology**. Sanofi will keep Fulcrum reasonably informed, through the JDC, regarding any Background Patents Controlled by Sanofi or its Affiliates that Sanofi reasonably anticipates Covering or incorporating, or has incorporated, in a Licensed Product, and that do not constitute Sanofi Manufacturing Technology. In addition, at Fulcrum's request no more frequently than once per Calendar Quarter, Sanofi will provide Fulcrum with reasonably high-level answers to questions regarding Background Know-How Controlled by Sanofi or its Affiliates that Sanofi reasonably anticipates Covering or incorporating, or has incorporated, in a Licensed Product, and that does not constitute Sanofi Manufacturing Technology. If, at any time during the Term, Fulcrum elects to receive a license to any Sanofi Technology that does not constitute Sanofi Manufacturing Technology, Fulcrum shall send written notice to Sanofi and, on Sanofi's receipt of such notice, (a) such Sanofi Technology shall be deemed to be "**Licensed Sanofi Technology**" under this Agreement, (b) such Licensed Sanofi Technology will be deemed to be "Controlled" under this Agreement (if the definition of "Control" is otherwise met) as Licensed Sanofi Technology licensed or sublicensed (as applicable) to Fulcrum under the license granted in Section 2.2 (*License Grants to Fulcrum*), subject to the terms of this Agreement, and (c) Sanofi will transfer or otherwise provide Fulcrum with access to any Know-How included in such Sanofi Technology to enable Fulcrum to exercise its right

under the license granted in Section 2.2 (*License Grants to Fulcrum*) to such Sanofi Technology. For clarity, any Sanofi Technology under which Fulcrum does not elect to receive a license shall not be deemed Licensed Sanofi Technology and shall not be included in the license grant to Fulcrum in Section 2.2.3 (*License Grants to Fulcrum*).

2.11.2 **Manufacturing Technology**.

(a) If either Party proposes amending the Global Development Plan to include the use or incorporation of any Sanofi Manufacturing Technology, then, as part of the JDC's review and discussion of such proposed amendment, the Parties will discuss whether Sanofi shall, in its sole discretion, (i) license such Sanofi Manufacturing Technology to Fulcrum, or (ii) Manufacture and supply Licensed Products incorporating such Sanofi Manufacturing Technology for Fulcrum and prior to the JDC approving any amendment to the Global Development Plan to include such Sanofi Manufacturing Technology, Sanofi will confirm whether such Sanofi Manufacturing Technology will be licensed to Fulcrum pursuant to Section 2.11.2(b) or if Sanofi will supply Fulcrum pursuant to Section 2.11.2(c).

(b) If the JDC amends the Global Development Plan to include the use or incorporation of any Sanofi Manufacturing Technology and Sanofi has elected to *license* such Sanofi Technology to Fulcrum, then (i) such Sanofi Manufacturing Technology shall be deemed to be "Licensed Sanofi Technology" under this Agreement, (ii) such Licensed Sanofi Technology will be deemed to be "Controlled" under this Agreement (if the definition of "Control" is otherwise met) as Licensed Sanofi Technology licensed or sublicensed (as applicable) to Fulcrum under the license granted in Section 2.2.3 (*License Grants to Fulcrum*), subject to the terms of this Agreement, and (iii) Sanofi will transfer or otherwise provide Fulcrum with access to any Know-How included in such Sanofi Manufacturing Technology to enable Fulcrum to exercise its right under the license granted in Section 2.2 (*License Grants to Fulcrum*) to such Sanofi Manufacturing Technology.

(c) If the JDC amends the Global Development Plan to include the use or incorporation of any Sanofi Manufacturing Technology and Sanofi has elected to Manufacture and supply Licensed Products incorporating such Sanofi Manufacturing Technology for Fulcrum instead of licensing such Sanofi Manufacturing Technology pursuant to Section 2.11.2(b), then the Parties will negotiate in good faith and enter into (i) a supply agreement on reasonable and customary terms under which Sanofi will Manufacture and supply Fulcrum with any Licensed Compound and Licensed Product in bulk unlabeled form that is necessary for Fulcrum to conduct its activities under the Fulcrum Independent Development Plan and Global Development Plan and Commercialize Licensed Compounds and Licensed Products in the Fulcrum Territory; *provided*, that Fulcrum will pay Sanofi a price equal to [***] of Sanofi's Manufacturing Cost for such Licensed Compounds and Licensed Products; and (ii) a related quality agreement, which agreement will govern the terms and conditions of the Manufacturing and supply of the Licensed Compounds or Licensed Products.

2.11.3 **License Terms**. On Fulcrum's election to receive a license to any Licensed Sanofi Technology under Section 2.11.1 (*Non-Manufacturing Technology*), or Sanofi's election to grant a license to any Sanofi Manufacturing Technology under Section 2.11.2

(*Manufacturing Technology*), the Parties shall negotiate in good faith [***] such license, determined in accordance with customary industry practice. If the Parties cannot agree on [***] within a period of [***] of receipt by Sanofi of Fulcrum's written notice that Fulcrum intends to exercise its rights with respect to the Licensed Sanofi Technology, then such dispute shall be referred to the Executive Officers of the Parties for resolution. If the Executive Officers do not fully resolve such dispute within [***] (or a later date agreed to by each of the Parties) of the dispute being referred to them then [***] shall be decided by baseball arbitration pursuant to the terms set forth on **Schedule 14.8.1(a)** (*Baseball Arbitration Terms*).

ARTICLE 3
GOVERNANCE

3.1 Joint Steering Committee.

3.1.1 **Formation and Purpose of the JSC**. Promptly, but not more than [***] after the Effective Date, Fulcrum and Sanofi will establish a joint steering committee ("**JSC**"), which will have the responsibilities set forth in this Article 3 (*Governance*) and will coordinate and discuss the Parties' Development, Manufacturing, and Commercialization activities under this Agreement for the Licensed Compounds and Licensed Products in the Territory in accordance with this Section 3.1 (*Joint Steering Committee*). The JSC will dissolve upon the expiration of the Term.

3.1.2 **Membership**. The JSC will be composed of an equal number of representatives from each Party and a minimum of [***] representatives of each Party who have the appropriate and direct knowledge and expertise and requisite decision-making authority. Any such representative who serves on the JSC or any committee under this Agreement may also serve on one or more other committees under this Agreement. Each Party may replace any of its representatives on the JSC and appoint a person to fill the vacancy arising from each such replacement. A Party that replaces a representative will notify the other Party in writing (with email correspondence being sufficient for such purpose) at least [***] prior to the next scheduled meeting of the JSC. Fulcrum will designate one (1) of its JSC members as one of the co-chairpersons of the JSC and Sanofi will designate one (1) of its members as the other co-chairperson of the JSC. Every [***] the co-chairpersons will alternate serving in the role of "lead co-chairperson." The lead co-chairperson or his or her designee, in collaboration with the Alliance Managers, will be responsible for calling meetings, preparing and circulating an agenda in advance of each meeting, and preparing and issuing draft minutes of each meeting within [***] thereafter. Such minutes will not be finalized until all JSC members have had [***] to review and confirm the accuracy of such minutes.

3.1.3 **Meetings**. The JSC will hold meetings at such times as it elects to do so, but will meet no less frequently than quarterly, unless otherwise agreed by the Parties. The JSC may meet in person or by means of teleconference, Internet conference, video conference, or other similar communication method; *provided* that, if practicable and permissible in light of any then applicable travel restrictions, at least [***] each Calendar Year will be conducted in person at a location selected alternatively by Fulcrum and Sanofi or such other location as the Parties may agree. Each Party will be responsible for all of its own costs and expenses of participating in any JSC meeting.

3.1.4 **Meeting Agendas**. Each Party will disclose to the other Party the proposed agenda items along with appropriate information at least [***] in advance of each meeting of the JSC; *provided* that under exigent circumstances requiring JSC input, a Party may provide its agenda items to the other Party within a shorter period of time in advance of a meeting, or may propose that there not be a specific agenda for a particular meeting, so long as such other Party consents to such later addition of such agenda items or the absence of a specific agenda for such JSC meeting.

3.1.5 **Specific Responsibilities of the JSC**. The responsibilities of the JSC will be to:

(a) manage the overall strategic alignment between the Parties under this Agreement and maintain the relationship between the Parties;

(b) review, discuss, and determine whether to approve any amendment to the Global Development Plan or Global Development Budget (including any amendments in connection with Additional Activities and Additional LC Activities), as described in Section 5.2 (*Initial Global Development Plan*) and Section 5.3 (*Changes to the Global Development Plan*);

(c) review and discuss any matters related to the Development of the Licensed Compounds and Licensed Products referred to the JSC by either Party's representatives or the JDC;

(d) review and discuss any matters related to the Commercialization of the Licensed Products in the Sanofi Territory or the Fulcrum Territory (including whether to approve the Joint Commercialization Strategy and joint publication strategy relating to Clinical Trials conducted under the Global Development Plan) referred to the JSC by either Party's representatives or the JCC;

(e) review and discuss any matters related to the Manufacture of the Licensed Products referred to the JSC by either Party's representatives or the JMC;

(f) establish and delegate specifically defined duties to the JDC, JMC, JCC, or other operational committees or *ad hoc* subcommittees, as described in Section 3.5.1 (*Formation; Authority*);

(g) attempt to resolve any disputes or disagreements arising from matters within the jurisdiction of any Subcommittee; and

(h) fulfill such other responsibilities as may be allocated to the JSC under this Agreement or through mutual written agreement of the Parties.

3.2 Joint Development Committee.

3.2.1 **Formation and Purpose of the JDC**. Promptly, but not more than [***] after the Parties establish the JSC, the JSC will establish a joint development committee ("**JDC**"), which will be a Subcommittee of the JSC and will have the responsibilities set forth in this Article 3 (*Governance*). The JDC will dissolve upon completion of all Development activities under this Agreement with respect to the Licensed Compounds and Licensed Products.

3.2.2 **Membership of the JDC**. Each Party will designate [***] representatives with appropriate knowledge, expertise, and decision-making authority to serve as members of the JDC. Each Party may replace its JDC representatives and co-chairpersons at any time upon written notice (with email correspondence being sufficient for such purpose) to the other Party. The Alliance Manager of each Party (or his or her designee) will attend each meeting of the JDC as a non-voting participant.

3.2.3 **Specific Responsibilities of the JDC**. The responsibilities of the JDC will be to:

(a) discuss Development activities under the Global Development Plan for the Licensed Compounds and Licensed Products under this Agreement;

(b) review and discuss the inclusion of any Sanofi Technology, as described in Section 2.11 (*Licensed Sanofi Technology*);

(c) (i) review and discuss the Global Development Plan and Global Development Budget, and (ii) prepare, review, discuss, and determine whether to recommend for JSC approval all updates to the Global Development Plan and Global Development Budget (including any updates in connection with Additional Activities and Additional LC Activities);

(d) review, discuss, and determine whether to approve each of the Sanofi Independent Development Plan and Fulcrum Independent Development Plan, and prepare, review, discuss, and determine whether to approve all updates thereto, as described in Section 5.5 (*Sanofi Independent Development Plan*) and Section 5.6 (*Fulcrum Independent Development Plan*), respectively;

(e) share information related to, and review and discuss activities and progress under, the Global Development Plan, the Sanofi Independent Development Plan and the Fulcrum Independent Development Plan, including through updates from each Party as to the status of Development for the Licensed Products in each Party's Territory, as described in Section 5.8 (*Development Reports*);

(f) review and discuss the overall strategy regarding Regulatory Submissions and Regulatory Approval of the Licensed Products throughout the Fulcrum Territory and Sanofi Territory, and discuss the implementation of, and progress regarding, the same; and

(g) fulfill such other responsibilities as may be allocated to the JDC under this Agreement or through mutual written agreement of the Parties.

3.3 Joint Manufacturing Committee.

3.3.1 **Formation and Purpose of the JMC**. Promptly, but not more than [***] after the Parties establish the JSC, the JSC will establish a joint manufacturing committee (the "**JMC**"), which will be a Subcommittee of the JSC and will have the responsibilities set forth in this Article 3 (*Governance*). The JMC will dissolve upon the completion of the Manufacturing Technology Transfer for Losmapimod.

3.3.2 **Membership of the JMC**. Each Party will designate [***] representatives with appropriate knowledge, expertise, and decision-making authority to serve as members of

the JMC. Each Party may replace its JMC representatives and co-chairpersons at any time upon written notice (with email correspondence being sufficient for such purpose) to the other Party. The Alliance Manager of each Party (or his or her designee) will attend each meeting of the JMC as a non-voting participant.

3.3.3 **Specific Responsibilities of the JMC**. The responsibilities of the JMC will be to:

(a) coordinate and discuss the Manufacturing Technology Transfer pursuant to Section 8.3 (*Manufacturing Technology Transfer*); and

(b) fulfill such other responsibilities (such as joint quality review) as may be allocated to the JMC under this Agreement or through mutual written agreement of the Parties.

3.4 Joint Commercialization Committee.

3.4.1 **Formation and Purpose of the JCC**. Promptly, but not more than [***] after the Parties establish the JSC, the JSC will establish a joint commercialization committee (the "**JCC**"), which will be a Subcommittee of the JSC and will have the responsibilities set forth in this Article 3 (*Governance*). The JCC will dissolve upon the expiration of the Term.

3.4.2 **Membership of the JCC**. Each Party will designate [***] representatives with appropriate knowledge, expertise, and decision-making authority to serve as members of the JCC. Each Party may replace its JCC representatives and co-chairpersons at any time upon written notice (with email correspondence being sufficient for such purpose) to the other Party. The Alliance Manager of each Party (or his or her designee) will attend each meeting of the JCC as a non-voting participant.

3.4.3 **Specific Responsibilities of the JCC**. The responsibilities of the JCC will be to:

(a) prepare, review, discuss and determine whether to recommend for JSC approval a high-level strategy for Commercialization of Licensed Products in the Sanofi Territory and the Fulcrum Territory, which strategy shall be limited to (i) a high-level summary of the Commercialization activities; and (ii) (A) selection of a single brand name to be used in the Territory, (B) registration and use of Trademarks and trade dress as agreed by each Party's Trademark counsel, and (C) determination of marketing positioning, in each case ((i) through (ii)), to be complied with by the Parties or its Affiliates or its or their Sublicensees for the Commercialization of a Licensed Product (the "**Joint Commercialization Strategy**");

(b) prepare, review, discuss and determine whether to recommend for JSC approval a joint publication strategy relating to Clinical Trials conducted under the Global Development Plan (including any publications, abstracts, presentations, conferences or congresses), including review and discussion of proposed publications and attempt to resolve disputes with respect thereto;

(c) subject to Applicable Law, facilitate information sharing and cooperation between the Parties with respect to the Commercialization activities for the Licensed Products in the Sanofi Territory and the Fulcrum Territory solely as necessary for the Parties to ensure compliance with the Joint Commercialization Strategy; and

(d) fulfill such other responsibilities as may be allocated to the JCC under this Agreement or through mutual written agreement of the Parties.

For clarity, the Parties shall have no obligation to discuss or share any information with respect to Commercialization, branding or marketing activities in the Sanofi Territory or the Fulcrum Territory, except as set forth in the Joint Commercialization Strategy.

3.5 Additional Committees.

3.5.1 **Formation; Authority**. The JSC will establish and delegate specifically-defined duties to the JDC, the JMC, the JCC, and other operational committees or *ad hoc* subcommittees, on an "as needed" basis to discuss particular projects or activities (the JDC, the JMC, the JCC and such other operational committees and subcommittees, each a "**Subcommittee**"). Each such Subcommittee, other than the JDC, the JMC and the JCC, will be constituted and will operate as the JSC determines. Each Subcommittee and its activities will be subject to the oversight of, and will report to, the JSC. The JSC or the co-chairpersons of the JSC may delegate to a Subcommittee any responsibilities of the JSC set forth in Section 3.1.5 (*Specific Responsibilities of the JSC*), and in such case, any agreement reached by unanimous Party Vote of the applicable Subcommittee with respect to such delegated responsibilities will be deemed to be approved by the JSC (to the extent such approval is required hereunder). The JSC or the co-chairpersons of the JSC acting together may also reallocate any responsibility of a Subcommittee to any other Subcommittee. No Subcommittee's authority may exceed that specified for the JSC in this Article 3 (*Governance*). Any disagreement between the representatives of the Parties on a Subcommittee will be referred to the JSC for resolution in accordance with Section 3.8 (*Resolution of Committee Disputes*).

3.5.2 **Subcommittee Leadership and Meetings**. Fulcrum will designate a co-chairperson of each Subcommittee and Sanofi will designate a co-chairperson of each Subcommittee, each of whom will be a Party's representative who is a member of such Subcommittee. Every [***] the co-chairpersons of each Subcommittee will alternate serving in the role of "lead co-chairperson." The lead co-chairperson or his or her designee, in collaboration with the Alliance Managers, will be responsible for calling meetings, preparing and circulating an agenda in advance of each meeting, and preparing and issuing minutes of each meeting within [***] thereafter. Such minutes will not be finalized until all Subcommittee members have had an adequate opportunity to review and confirm the accuracy of such minutes in writing. Each Party may replace its representatives and co-chairpersons on each such Subcommittee at any time upon written notice (with email correspondence being sufficient for such purpose) to the other Party. The Alliance Manager of each Party (or his or her designee) will attend each meeting of each Subcommittee as a non-voting participant. Each Subcommittee will hold meetings at such times as it elects to do so (but in any event at least [***] with respect to the JDC, the JMC and the JCC and at least [***] a year for all other Subcommittees, unless the Parties agree otherwise), and at such locations as the Parties may agree upon or, if agreed by the Parties, by audio or video teleconference. Each Party will be responsible for all of its own expenses of participating in any Subcommittee meeting.

3.5.3 **Operational Teams**. From time-to-time, the JSC or any Subcommittee may establish and delegate specific matters or duties within its responsibilities to directed teams (each, an "**Operational Team**"), the composition, operation, and responsibilities of which will be determined by the JSC or the applicable establishing Subcommittee (the "**Establishing**

Committee"). Operational Teams may be established on an *ad hoc* basis for purposes of a specific activity or on such other basis as the applicable Establishing Committee may determine. Each Operational Team will report to, and its activities will be subject to the oversight of, the applicable Establishing Committee. No Operational Team's authority may exceed that specified for the applicable Establishing Committee. Any disagreement between the representatives of the Parties on any Operational Teams will be referred to the applicable Establishing Committee for resolution in accordance with Section 3.8 (*Resolution of Committee Disputes*).

3.6 Additional Participants. Employees of a Party or any of its Affiliates involved in the Exploitation of the Licensed Compounds and Licensed Products may attend meetings of the JSC or any Subcommittee as non-voting participants with the prior consent of the other Party. In addition, with the prior consent of each Party (with email correspondence being sufficient for such purpose), consultants, representatives, or advisors involved in the same activities and under written obligations of confidentiality and non-use applicable to the Confidential Information of each Party that are at least as stringent as those set forth in Article 12 (*Confidentiality*) may attend meetings of the JSC or any Subcommittee as non-voting observers.

3.7 Decision-Making.

3.7.1 **General Decision-Making Process**. Each Party's representatives on the JSC and each Subcommittee will, collectively, have one vote (the "**Party Vote**") on all matters brought before such committee for a decision by consensus. The JSC and each Subcommittee will make decisions as to matters within its jurisdiction by unanimous Party Vote, which may be reflected in the minutes of the committee meeting or by an action by written consent signed by the co-chairperson appointed by each Party or his or her designee identified in writing (for the purpose of this Section 3.7.1 (*General Decision-Making Process*), consent via email will be allowed). Except as otherwise expressly set forth in this Agreement, the phrase "determine," "designate," "align," "approve," or "determine whether to approve" by the JSC or any Subcommittee and similar phrases used in this Agreement will mean approval in accordance with this Section 3.7 (*Decision-Making*), including the escalation and tie-breaking provisions herein. For the avoidance of doubt, matters that are specified in Section 3.1.5 (*Specific Responsibilities of the JSC*), Section 3.2.3 (*Specific Responsibilities of the JDC*), Section 3.3.3 (*Specific Responsibilities of the JMC*) or Section 3.4.3 (*Specific Responsibilities of the JCC*) to be reviewed and discussed (as opposed to reviewed, discussed, and approved) do not require any agreement or decision by either Party and are not subject to the voting and decision-making procedures set forth in this Section 3.7 (*Decision-Making*) or Section 3.8 (*Resolution of Committee Disputes*).

3.7.2 **Decisions of the Subcommittees**. If the Alliance Managers or any Subcommittee cannot reach unanimous agreement using good faith efforts on any matter within their respective scope of authority within [***] of the meeting at which such matter was discussed, then a Party may refer such matter to the JSC for resolution in accordance with Section 3.7.3 (*Decisions of the JSC*); *provided*, *however*, that a Party shall refer any such matter relating to the approval of the Sanofi Independent Development Plan or the Fulcrum Independent Development Plan, or any update thereto, to the Party's respective Executive Officer for resolution in accordance with Section 3.8.1 (*Referral to Executive Officers*).

3.7.3 **Decisions of the JSC**. The JSC will use good faith efforts, in compliance with this Section 3.7.3 (*Decisions of the JSC*), to promptly resolve any such matter for which it has authority. If, after the use of good faith efforts, the JSC is unable to resolve any such matter referred

to it by any Subcommittee or any matter with respect to the matters within the scope of the JSC's authority or any other disagreement between the Parties that may be referred to the JSC, in each case, within a period of [***], then a Party may refer such matter to the Party's respective Executive Officer for resolution in accordance with Section 3.8.1 (*Referral to Executive Officers*).

3.8 Resolution of Committee Disputes.

3.8.1 **Referral to Executive Officers**. If a Party makes an election under Section 3.7.3 (*Decisions of the JSC*) or the proviso under Section 3.7.2 (*Decisions of the Subcommittees*) to refer for resolution by the Executive Officers a matter as to which the JSC or the JDC cannot reach a consensus decision, then the JSC or the JDC, as applicable, will submit in writing the respective positions of the Parties to their respective Executive Officers. The Executive Officers will use good faith efforts to resolve any such matter so referred to them as soon as practicable but in any event within [***] after such matter is referred to them, and any final decision that the Executive Officers agree to in writing will be conclusive and binding on the Parties.

3.8.2 **Final Decision-Making Authority**. If the Executive Officers are unable to reach agreement on any such matter so referred within [***] after such matter is referred to them (or such longer period as the Executive Officers may agree upon), then, subject to Section 3.8.3 (*Limitations on Decision Making*):

(a) **No Change; Status Quo**. Neither Party will have final decision-making authority with respect to the final resolution of any disagreement that is not subject to Fulcrum's final decision making authority under Section 3.8.2(b) (*Fulcrum Final Decision-Making Authority*), or Sanofi's final decision making authority under Section 3.8.2(c) (*Sanofi Final Decision-Making Authority*), including any disagreement related to the approval of (i) any update to the Global Development Plan or Global Development Budget, (ii) the initial Joint Commercialization Strategy or any update thereto, or (iii) the initial joint publication strategy or any update thereto. Additionally, neither Party will have final decision-making authority with respect to the finalization of the initial budget for the Open Budget Studies, which will be resolved pursuant to Section 3.8.2(d) (*Final Decision-Making Authority for Open Budget Studies*).

(b) **Fulcrum Final Decision-Making Authority**. Fulcrum will have final decision-making authority over:

(i) all matters related to the Fulcrum Independent Development Program, including approval of the Fulcrum Independent Development Plan and any updates thereto, (A) *provided* that the Fulcrum Independent Development Plan is at all times consistent with the Global Development Plan and (B) except to the extent Fulcrum's conduct of the Fulcrum Independent Development Activities (including any Additional Activities conducted by or on behalf of Fulcrum pursuant to Section 5.3.1(c)(i) (*Additional Activities under Global Development Plan*)) has a Material Adverse Effect with respect to Sanofi, *provided* that any dispute over whether Fulcrum's conduct has such a Material Adverse Effect with respect to Sanofi shall be resolved in accordance with Section 15.1 (*Dispute Resolution*),

(ii) all matters to the extent related to the Commercialization of Licensed Product in the Fulcrum Territory, including matters related to the use of the Fulcrum Product Trademarks or Trademarks deemed to be Sanofi Product Trademarks under Section 10.11.1(c) (*Jointly-Determined Brand Names*) in the Fulcrum Territory (*provided* that such Commercialization is at all times consistent with the Joint Commercialization Strategy), and

(iii) all matters that are solely related to the day-to-day execution of Clinical Trials of the Licensed Compounds and Licensed Products sponsored solely by Fulcrum or its Affiliates under the Global Development Plan (*provided* that such execution is at all times consistent with the Global Development Plan),

in each case ((i)-(iii)), solely to the extent such matters are not subject to Sanofi's final decision-making authority under Section 3.8.2(c) (*Sanofi Final Decision-Making Authority*).

(c) **Sanofi Final Decision-Making Authority**. Sanofi will have final decision-making authority over:

(i) all matters related to the Sanofi Independent Development Program, including approval of the Sanofi Independent Development Plan and any updates thereto, (A) *provided* that the Sanofi Independent Development Plan is at all times consistent with the Global Development Plan and (B) except to the extent Sanofi's conduct of the Sanofi Independent Development Activities (including any Additional Activities conducted by or on behalf of Sanofi or its Affiliates pursuant to Section 5.3.1(c)(i) (*Additional Activities under Global Development Plan*)) has a Material Adverse Effect with respect to Fulcrum, *provided* that any dispute over whether Sanofi's conduct has such a Material Adverse Effect with respect to Fulcrum shall be resolved in accordance with Section 15.1 (*Dispute Resolution*),

(ii) all matters to the extent related to the Commercialization of Licensed Product in the Sanofi Territory, including matters related to the use of the Sanofi Product Trademarks in the Sanofi Territory (*provided* that such Commercialization is at all times consistent with the Joint Commercialization Strategy), and

(iii) all matters that are solely related to the day-to-day execution of Clinical Trials of the Licensed Products sponsored by Sanofi or its Affiliates under the Global Development Plan (*provided* that the Sanofi Independent Development Plan is at all times consistent with the Global Development Plan),

in each case ((i)-(iii)), solely to the extent such matters are not subject to Fulcrum's final decision-making authority under Section 3.8.2(b) (*Fulcrum Final Decision-Making Authority*).

(d) **Final Decision-Making Authority for Open Budget Studies**. If the disagreement is with respect to the approval of the initial budget for any Open Budget Study,

then the initial budget for such Open Budget Study shall be decided by baseball arbitration pursuant to the terms set forth on **Schedule 14.8.1(a)** (*Baseball Arbitration Terms*).

3.8.3 **Limitations on Decision-Making**. Notwithstanding the creation of the JSC or any Subcommittee and anything to the contrary set forth in this Agreement, (a) no decision of the JSC, any Subcommittee, or a Party's Executive Officer (in the exercise of a Party's decision-making authority on any such matters), in each case would, without the other Party's prior written consent, (i) result in a material increase in the other Party's obligations, costs, or expenses under this Agreement or the Global Development Budget, (ii) require such other Party to violate any Applicable Law, the requirements of any Regulatory Authority, or any agreement with any Third Party (including any Collaboration In-License) or infringe or misappropriate the intellectual property rights of any Third Party, or (iii) conflict with, amend, interpret, modify, or waive compliance under this Agreement; and (b) each Party will retain the rights, powers and discretion granted to it hereunder, and none of the JSC or any Subcommittee will be delegated or vested with such rights, powers or discretion unless such delegation or vesting is expressly provided herein, or the Parties expressly so agree in writing. It is understood and agreed that issues to be formally decided by the JSC or any Subcommittee are limited to those specific issues that are expressly provided in Section 3.1.5 (*Specific Responsibilities of the JSC*), Section 3.2.3 (*Specific Responsibilities of the JDC)* and Section 3.3.3 (*Specific Responsibilities of the JMC*), and that disputes which relate to subjects other than those expressly set forth in the foregoing Sections will be handled according to Section 15.1 (*Dispute Resolution*).

3.9 Alliance Managers. Each of the Parties will appoint a single individual to manage Development and Commercialization obligations between the Parties no later than [***] after the Effective Date (each, an "**Alliance Manager**"). The role of the Alliance Manager is to act as a single point of contact between the Parties to ensure a successful relationship under this Agreement. The Alliance Managers will attend all JSC meetings and the Alliance Managers or their respective designees will attend all Subcommittee meetings and will support the co-chairpersons of the JSC and each Subcommittee in the discharge of his or her responsibilities. Alliance Managers will be non-voting participants in all JSC and Subcommittee meetings, but an Alliance Manager may bring any matter to the attention of the JSC or any Subcommittee if such Alliance Manager reasonably believes that such matter warrants such attention. Each Party will designate its initial Alliance Manager promptly after the Effective Date and each Party may change its designated Alliance Manager at any time upon written notice to the other Party. Any Alliance Manager may designate a substitute to temporarily perform the functions of that Alliance Manager by written notice to the other Party. Each Alliance Manager will also: (a) be the point of first referral in all matters of conflict resolution; (b) provide a single point of communication for seeking consensus between the Parties regarding key strategy and plan issues; (c) identify and bring disputes to the attention of the JSC in a timely manner; (d) plan and coordinate cooperative efforts and internal and external communications; and (e) take responsibility for ensuring that governance activities, such as the conduct of required JSC and Subcommittee meetings and production of meeting minutes, occur as set forth in this Agreement, and that the relevant action items resulting from such meetings are appropriately carried out or otherwise addressed.

ARTICLE 4
TECHNOLOGY TRANSFER

4.1 Initial Technology Transfer. Promptly after the Effective Date, but in any event within [***] therefrom, Fulcrum will provide and transfer to Sanofi copies that exist as of the Effective Date of:

(a) all Research results, data, information and Regulatory Submissions, in each case, relating to the Development of the Licensed Compounds and Licensed Products, (b) the Fulcrum Materials and (c) copies of the documents, in the case of clauses (a) and (c), within the Fulcrum Know-How, and in the case of clauses (a) and (b), as set forth in **Schedule 4.1** (*Initial Technology Transfer*) (the "**Initial Technology Transfer**"). Fulcrum may make the foregoing in clauses (a) through (c) available in such reasonable form as maintained by Fulcrum.

4.2 Continuing Technology Transfer. Following the Initial Technology Transfer for the Licensed Compounds and Licensed Products, Fulcrum will provide to the JSC in advance of the last JSC meeting for each Calendar Quarter a summary of any additional Fulcrum Know-How and Fulcrum Materials developed by Fulcrum or its Affiliates since the previous quarterly disclosure. Upon Sanofi's reasonable request during the Term, Fulcrum will make available to Sanofi all such Fulcrum Know-How and Fulcrum Materials in Fulcrum's possession and not previously provided to Sanofi hereunder (the "**Continuing Technology Transfer**," and together with the Initial Technology Transfer, the "**Technology Transfer**").

4.3 Assistance. Fulcrum will, and will cause its Affiliates to, reasonably cooperate with Sanofi and its designees and provide assistance to Sanofi and its designees to transition to Sanofi and its designees the Research, Development, Manufacture, Commercialization and other Exploitation of each Licensed Compound and Licensed Product, as and to the extent reasonably requested by Sanofi. Without limiting the foregoing, Fulcrum will: (a) provide Sanofi and its designees assistance with respect to Research and Development (including regulatory) transition matters related to such Licensed Compounds or Licensed Products; and (b) provide Sanofi and its designees with reasonable access by teleconference (or, to the extent reasonably requested by Sanofi, in-person meetings) to Fulcrum personnel and personnel of Fulcrum's Affiliates and will use Commercially Reasonable Efforts to provide reasonable access to Third Party contractors involved in Research or Development (including regulatory) matters related to such Licensed Compounds or Licensed Products to assist with the transition and answer questions related to such Licensed Compounds or Licensed Products.

4.4 Technology Transfer Costs. Fulcrum (a) will conduct the Technology Transfer and (b) will provide assistance in connection with such Technology Transfer as set forth in Section 4.3 (*Assistance*), in each case ((a) and (b)), at no cost to Sanofi until and unless [***] hours of assistance have been provided by Fulcrum, after which time Sanofi will reimburse Fulcrum for Internal Costs and External Costs, in each case, reasonably incurred by or on behalf of Fulcrum in connection with such Technology Transfer within [***] after receiving Fulcrum's invoice therefor.

ARTICLE 5
DEVELOPMENT

5.1 Development Obligations. Fulcrum will use Commercially Reasonable Efforts to [***]. Without limiting Fulcrum's rights under Section 14.2 (*Termination for Material Breach*) to terminate this Agreement in its entirety but notwithstanding any other provision in this Agreement, [***]. Each Party will conduct all Development activities for which it is responsible under this Agreement in a good scientific manner, in accordance with GLP and GCP, as applicable, and in compliance with Professional Requirements and Applicable Law.

5.2 Initial Global Development Plan. The initial global development plan and corresponding budget for the Licensed Compounds and Licensed Products is set forth on **Schedule 5.2** (*Initial Global Development Plan and Budget*) (such global development plan attached as of signing, the "**Initial Global Development Plan**" and as it may be modified in accordance with the terms and conditions

of this Agreement, the "**Global Development Plan**" and such corresponding budget, the "**Global Development Budget**"). The Initial Global Development Plan includes (and will at all times include): (a) all Research and Development activities for the Licensed Compounds and Licensed Products other than (i) Research or Development activities that are solely intended to support obtaining or maintaining Regulatory Approval or label expansion of the Licensed Compounds and Licensed Products in the Sanofi Territory (such excluded Research and Development activities in clause (i), "**Sanofi Independent Development Activities**") and (ii) Research or Development activities that are solely intended to support obtaining or maintaining Regulatory Approval or label expansion of the Licensed Compounds and Licensed Products in the Fulcrum Territory (such excluded Research and Development activities in clause (ii), "**Fulcrum Independent Development Activities**"), (b) the allocation of responsibilities between the Parties for all activities under the Global Development Plan, and (c) the estimated timelines for all activities under the Global Development Plan. The Global Development Budget also includes (and will at all times include) a detailed written budget for the performance of the activities under the Global Development Plan for the current Calendar Year and at least [***] subsequent Calendar Years, broken down by Calendar Year; *provided* that, with respect to the Global Development Budget included in the Initial Global Development Plan, the budget for the performance of any Clinical Trials that are identified as "Open Budget Studies" in the Global Development Budget included in the Initial Global Development Plan (each such Clinical Trial, an "**Open Budget Study**") will be reviewed, discussed, and approved by the JSC promptly after the Effective Date.

5.3 Changes to the Global Development Plan.

5.3.1 **Additional Activities under Global Development Plan**. Except as otherwise set forth in Section 5.3.2 (*Development of Additional Licensed Compounds*):

(a) Either Party (the "**Proposing Party**") may, from time to time during the Term, submit to the JDC any proposed update to (i) the Global Development Plan to include additional Research and Development activities (or to otherwise update the Research and Development activities) for the Licensed Compounds and Licensed Products other than Sanofi Independent Development Activities or Fulcrum Independent Development Activities and (ii) the Global Development Budget to correspond with any changes to the Global Development Plan contemplated in the foregoing clause (i) (any such additional Research and Development activity, "**Additional Activity**"). The JDC will review, discuss, and determine whether to approve each update with respect to an Additional Activity to the Global Development Plan and the Global Development Budget and will submit any such update to the JSC to review, discuss, and determine whether to approve.

(b) If approved by the JDC and JSC (as applicable), each update with respect to the applicable Additional Activity to the Global Development Plan or the Global Development Budget will become effective and supersede the previous Global Development Plan or Global Development Budget, as applicable, as of the date of such approval or at such other time as decided by the JSC.

(c) If the JDC and JSC (as applicable) do not approve an Additional Activity, then:

(i) The Proposing Party may conduct the Additional Activity, at its sole expense, as part of the Sanofi Independent Development Plan or Fulcrum Independent Development Plan, as applicable; *provided*, that such

Additional Activity is consistent at all times with the Global Development Plan, conducted in compliance with all Applicable Laws (including GLP, GCP, and GMP, as applicable), and would not have a Material Adverse Effect with respect to Sanofi if the Proposing Party is Fulcrum and Fulcrum if the Proposing Party is Sanofi.

(ii) The Proposing Party shall keep the non-Proposing Party reasonably informed as to the progress of the Additional Activity, including by providing updates on the progress of such Additional Activity at each JDC meeting in accordance with Section 5.8 (*Development Reports*).

(iii) Any information, data or other Know-How arising out of such Additional Activity will not be included as "Sanofi Know-How" under this Agreement if the Proposing Party is Sanofi or as "Fulcrum Know-How" if the Proposing Party is Fulcrum, in each case, unless the non-Proposing Party pays for such right under Section 5.3.1(c)(iv) (*Additional Activities under Global Development Plan*).

(iv) The non-Proposing Party will have the right, but not the obligation, to obtain access to and use of any information, data and other Know-How arising out of such Additional Activity on payment to the Proposing Party of an amount equal to [***] of its equal share of the actual Internal Costs and External Costs incurred by the Proposing Party or any of its Affiliates in connection with the Additional Activity (which costs, for clarity, shall thereafter be deemed Eligible Global Development Costs) as set forth in Section 5.7 (*Development Cost Sharing*).

5.3.2 **Development of Additional Licensed Compounds.** If at any time during the Term either Party or its Affiliates identifies any compound within its Control that it in good faith believes is reasonably likely to constitute a Licensed Compound (whether in the performance of its obligations under this Agreement or otherwise) (such compound, the "**Additional Compound**"), such Party shall promptly notify the JDC, which notice shall include a brief explanation as to how such Additional Compound was Developed and the basis of such Party's belief that such Additional Compound may constitute a Licensed Compound. The JDC will review, discuss, and determine whether to amend (i) the Global Development Plan to add the Research and Development activities necessary to support further Research and Development of such Additional Compound and (ii) the Global Development Budget to correspond with any changes to the Global Development Plan contemplated in the foregoing clause (i) (such activities, the "**Additional LC Activities**"), and will submit any such updates to the JSC. The JSC will review, discuss, and determine whether to approve the inclusion of any such Additional LC Activities in the Global Development Plan and Global Development Budget.

5.4 Sanofi Step-In Right under Global Development Plan. In the event that (a) Sanofi provides written notice to Fulcrum that (i) Sanofi reasonably believes Fulcrum is in material breach of or Material Delay with respect to its obligations under the Global Development Plan as a whole (which notice shall describe in reasonable detail reasons and facts in support of such belief), and (ii) Fulcrum fails to cure such breach or delay (or provides reasonably satisfactory evidence showing that Fulcrum is not in such breach or delay) within [***] from the date of Sanofi's notice of such breach or delay, or (b) [***], then Sanofi may elect by written notice to Fulcrum to assume the relevant activities originally assigned to Fulcrum under the Global Development Plan (the "

Step-In Activities"). In such case, the Parties will coordinate on transfer activities necessary or reasonably useful to enable Sanofi to assume such Step-In Activities (with the reasonable External Costs of such transfer activities to be borne by Fulcrum), including:

5.4.1 to the extent in Fulcrum's possession, transferring any quantities of Licensed Compound or Licensed Product, and Fulcrum Materials, as needed,

5.4.2 to the extent in possession of any Affiliates or subcontractors acting on behalf of Fulcrum under this Agreement as of the Effective Date or during the Term, directing such Affiliates or subcontractors to transfer any quantities of Licensed Compound or Licensed Product, and Fulcrum Materials, as needed, and

5.4.3 making available to Sanofi copies of all Regulatory Submissions and all information, data or other Know-How Controlled by Fulcrum not already provided to Sanofi that would enable Sanofi or its designee to perform such Step-In Activities.

In the event that Sanofi elects the step-in remedy pursuant to this Section 5.4 (*Sanofi Step-In Right under Global Development Plan*), then such remedy will be Sanofi's sole and exclusive remedy with respect to the applicable material breach or Material Delay that gave rise to Sanofi's right to elect such remedy, except that amounts incurred by Sanofi or its Affiliates in connection with such Step-In Activities shall be subject to cost sharing in accordance with Section 5.7 (*Development Cost Sharing*) to the extent such amounts are consistent with the then-current Global Development Budget for such Step-In Activities. Notwithstanding the foregoing, any material breach by Fulcrum as a result of a Force Majeure Event will not trigger Sanofi's step-in remedy under this Section 5.4 (*Sanofi Step-In Right under Global Development Plan*). For the purposes of Collaboration Technology ownership under this Agreement, all Collaboration Technology solely invented, developed or generated by or behalf of Sanofi or its Affiliates due to its exercise of the step-in right under this Section 5.4 (*Sanofi Step-In Right under Global Development Plan*) shall be owned by Sanofi, subject to Section 2.2 (*License Grants to Fulcrum*).

5.5 Sanofi Independent Development Plan. Within [***] following the Effective Date, Sanofi will prepare and submit to the JDC a plan setting forth (a) all Sanofi Independent Development Activities and (b) the estimated timelines for performing and completing such activities (the "**Sanofi Independent Development Plan**"). The JDC will review, discuss, and determine whether to approve the initial Sanofi Independent Development Plan. At least annually during the Term (and more frequently as may be necessary), Sanofi will prepare an update to the Sanofi Independent Development Plan to include the Sanofi Independent Development Activities to be conducted during the upcoming Calendar Year (or otherwise update such Research and Development activities). The JDC will review, discuss, and determine whether to approve each update to the Sanofi Independent Development Plan. Once approved by the JDC, the Sanofi Independent Development Plan and each update thereto will become effective and, in the case of an update, supersede the previous Sanofi Independent Development Plan as of the date of such approval or at such other time as decided by the JDC. Notwithstanding the foregoing or anything to the contrary in this Agreement, the Sanofi Independent Development Plan will not include Research and Development activities in the Global Development Plan.

5.6 Fulcrum Independent Development Plan. Within [***] following the Effective Date, Fulcrum will prepare and submit to the JDC a plan setting forth (a) all Fulcrum Independent Development Activities and (b) the estimated timelines for performing and completing such activities (the "**Fulcrum Independent Development Plan**"). The JDC will review, discuss, and determine whether to approve the initial Fulcrum Independent Development Plan. At least annually during

the Term (and more frequently as may be necessary), Fulcrum will prepare an update to the Fulcrum Independent Development Plan to include the Fulcrum Independent Development Activities to be conducted during the upcoming Calendar Year (or otherwise update such Research and Development activities). The JDC will review, discuss, and determine whether to approve each update to the Fulcrum Independent Development Plan. Once approved by the JDC, the Fulcrum Independent Development Plan and each update thereto will become effective and, in the case of an update, supersede the previous Fulcrum Independent Development Plan as of the date of such approval or at such other time as decided by the JDC. Notwithstanding the foregoing or anything to the contrary in this Agreement, the Fulcrum Independent Development Plan will not include Research and Development activities in the Global Development Plan.

5.7 Development Cost Sharing.

5.7.1 **Eligible Global Development Costs**. The Parties [***] all Eligible Global Development Costs in accordance with the procedures set forth in this Section 5.7.1 (*Eligible Global Development Costs*); *provided*, *however*, if the Global Development Costs incurred by a Party in conducting an activity assigned to it in the Global Development Plan exceed the Eligible Global Development Costs ("**Budget Overrun**"), then such incurring Party will be solely responsible for the amount of Budget Overrun and such Budget Overrun shall be excluded from the Eligible Global Development Costs, unless the JDC otherwise agrees that the Parties will [***] amount. No later than [***] after the end of each Calendar Quarter, each Party will deliver to the other Party a written report of the Eligible Global Development Costs incurred by or on behalf of such Party during such Calendar Quarter, together with reasonable supporting documentation (for Fulcrum, the "**Fulcrum Development Cost Share Notice**" and for Sanofi, the "**Sanofi Development Cost Share Notice**"). For each Calendar Quarter:

(a) **Fulcrum True-Up**. If the amount set forth in the Sanofi Development Cost Share Notice exceeds fifty percent (50%) of the total Eligible Global Development Costs reported by both Parties in their respective cost share notices for a particular Calendar Quarter, then no later than [***] after Fulcrum's receipt of the Sanofi Development Cost Share Notice for such Calendar Quarter and an invoice therefor, Fulcrum will make a balancing payment to Sanofi equal to [***] of the total Eligible Global Development Costs reported by both Parties in their respective cost share notices *minus* the amount set forth in Fulcrum Development Cost Share Notice, such that each Party bears [***]of the aggregate Eligible Global Development Costs incurred by or on behalf of the Parties in the performance of the Global Development Plan during such Calendar Quarter.

(b) **Sanofi True-Up**. If the amount set forth in the Fulcrum Development Cost Share Notice exceeds fifty percent (50%) of the total Eligible Global Development Costs reported by both Parties in their respective cost share notices for a particular Calendar Quarter, then no later than [***] after Sanofi's receipt of the Fulcrum Development Cost Share Notice for such Calendar Quarter and an invoice therefor, Sanofi will make a balancing payment to Fulcrum equal to [***] of the total Eligible Global Development Costs reported by both Parties in their respective cost share notices *minus* the amount set forth in Sanofi Development Cost Share Notice, such that [***] of the aggregate Eligible Global Development Costs incurred by or on behalf of the Parties in the performance of the Global Development Plan during such Calendar Quarter.

5.7.2 **Sanofi Independent Development Activities**. Subject to Section 5.3.1(c)(iii) (*Additional Activities under Global Development Plan*), Sanofi will be solely responsible for all costs and expenses incurred in connection with the performance of all Sanofi Independent Development Activities.

5.7.3 **Fulcrum Independent Development Activities**. Subject to Section 5.3.1(c)(iii) (*Additional Activities under Global Development Plan*), Fulcrum will be solely responsible for all costs and expenses incurred in connection with the performance of all Fulcrum Independent Development Activities.

5.8 Development Reports. At each JDC meeting, Fulcrum and Sanofi will each provide the JDC with a written summary of the activities conducted by or on behalf of such Party under, as applicable, the Global Development Program, the Sanofi Independent Development Program and the Fulcrum Independent Development Program since the last JDC meeting, including patient enrollment and the ongoing status of all Clinical Trials under the applicable plan. Each Party will also promptly provide written notice to the other Party, through the JDC or Alliance Managers, of any significant Research and Development events under the Global Development Program, the Sanofi Independent Development Program or the Fulcrum Independent Development Program that the reporting Party reasonably believes materially impacts the Research or Development activities of the other Party under this Agreement or is otherwise of interest to the other Party.

5.9 Development Records. Each Party and its Affiliates will maintain written or electronic records, in sufficient detail, in a good scientific manner (in accordance with GLP, GCP, and GMP, as applicable), and appropriate for regulatory and patent purposes, and that are complete and accurate in all material respects and reflect all Research and Development work performed and results achieved, in each case, by or on behalf of such Party and its Affiliates under the Global Development Program, the Sanofi Independent Development Program and the Fulcrum Independent Development Program.

ARTICLE 6
REGULATORY AFFAIRS

6.1 Regulatory Responsible Party. Prior to the Regulatory Responsibility Transfer Date, Fulcrum will be the Regulatory Responsible Party for the Licensed Products in the Territory. On and after the Regulatory Responsibility Transfer Date, Fulcrum will be the Regulatory Responsible Party for Licensed Products in the Fulcrum Territory, and Sanofi will be the Regulatory Responsible Party for the Licensed Products in the Sanofi Territory; *provided, however*, if a Party or its Affiliate, Sublicensee or subcontractor is sponsoring a Clinical Trial, such Party will the Regulatory Responsible Party for such Clinical Trial and will own all Regulatory Submissions for such Clinical Trial, except that Fulcrum will transfer ownership of any Regulatory Submissions for Clinical Trials conducted in the Sanofi Territory under the Global Development Plan in accordance with the succeeding sentence. Promptly, but in any event no later than [***] after the Effective Date, on a Licensed Product-by-Licensed Product basis, (a) unless not permitted by Applicable Law, Fulcrum will transfer ownership to Sanofi of all Regulatory Submissions (including the IND) with respect to a Licensed Product in the Sanofi Territory (including by providing true, accurate and complete electronic copies thereof to Sanofi); *provided* that Fulcrum will not transfer ownership of any Regulatory Submissions required for the conduct of the Fulcrum Sponsored Clinical Trials until, on a Clinical Trial-by-Clinical Trial basis, a Fulcrum Sponsored Clinical Trial is completed and Fulcrum's ownership of such Regulatory Submissions is no longer reasonably necessary to conduct and complete such Fulcrum Sponsored Clinical Trial and (b) within [***] following the completion of all activities set forth in the foregoing clause (a), Fulcrum will send a letter to each

Regulatory Authority as applicable to a specific country or jurisdiction to record and notify such Regulatory Authority of the transfer of ownership to Sanofi of all Regulatory Submissions with respect to the relevant Licensed Product in the Sanofi Territory (the date when all activities set forth in the foregoing clauses (a) and (b) under this Section 6.1 (*Regulatory Responsible Party*) are completed, each, a "**Regulatory Responsibility Transfer Date**"). In the event the transfer of ownership or assignment of any Regulatory Submissions is not permitted under Applicable Law, Fulcrum will hold such Regulatory Submissions in trust for, or for the sole benefit of, Sanofi. Subject to this Section 6.1 (*Regulatory Responsible* Party), effective from and after each Regulatory Responsibility Transfer Date, all Regulatory Submissions and Regulatory Approvals in the Sanofi Territory with respect to the relevant Licensed Product after the Regulatory Responsibility Transfer Date will be owned by and held in the name of Sanofi. For clarity, Fulcrum will not have any responsibility to transfer any Regulatory Submissions to Sanofi for any Clinical Trial conducted under the Fulcrum Independent Development Plan.

6.2 Collaboration With Respect to Regulatory Interactions.

6.2.1 **Correspondence**. The Regulatory Responsible Party will provide the other Party with (a) copies of any material written correspondence submitted to or received from the EMA, national health authorities within the E.U., FDA and MHLW, and (b) summaries of any material oral communications with the EMA, national health authorities within the E.U., FDA and MHLW, in each case ((a) and (b)), relating to Regulatory Submissions for the Licensed Products in such jurisdiction or country, reasonably promptly after receipt or delivery by such Regulatory Responsible Party of such correspondence or communication, as the case may be (but in any event, no later than [***] after receipt or delivery).

6.2.2 **Regulatory Responsibility**. The Regulatory Responsible Party will be responsible for, and will have final decision-making authority on the content of, all Regulatory Submissions, communications, and other dealings with the Regulatory Authorities relating to the Licensed Products in the applicable jurisdictions for which such Party is the Regulatory Responsible Party. The Regulatory Responsible Party will not be required to delay any submission, correspondence, or communication with any Regulatory Authorities in a manner that affects such Regulatory Responsible Party's ability to comply with any Regulatory Authority requirement or deadline or Applicable Law in such jurisdiction.

6.3 Regulatory Meetings. The applicable Regulatory Responsible Party will provide the other Party with as much advance notice as practicable under the circumstances, but in no event less than [***], to the extent practicable, notice for any meetings pertaining to Regulatory Submissions for the Licensed Products (to the extent such meetings are scheduled in advance) with the EMA, MHRA, FDA, and the MHLW, to the extent not prohibited by Applicable Law or the applicable Regulatory Authority. Unless otherwise prohibited under Applicable Law or by the relevant Regulatory Authority, the other Party will have the right to have its representatives attend all such meetings (other than any such meetings with the MHLW), with the specific number of representatives to be agreed upon by the Parties based on the agenda topics for such meetings and any requirements under Applicable Law, but in any event, no more than [***], with the goal of ensuring that the necessary subject matter experts from each Party attend any such meeting. Upon the other Party's request, the Regulatory Responsible Party will include the other Party in the preparation and strategy for substantive meetings with the EMA, MHRA, FDA, and the MHLW and in any discussions and actions relating to the outcome thereof. The Regulatory Responsible Party will take the lead and be primarily responsible for interactions with Regulatory Authorities at any such meeting attended by representatives of each Party. The non-Regulatory Responsible Party (i) will strictly follow the Regulatory Responsible Party's instructions with respect to any such meeting

that it attends and (ii) will not discuss the contents of any such meeting with any Third Party or Regulatory Authority except as required by Applicable Law or authorized by the Regulatory Responsible Party in writing.

6.4 Regulatory Submissions. Each Party will provide the other Party with a copy of all proposed material Regulatory Submissions to be filed with or submitted to EMA, national health authorities within the E.U., FDA and MHLW for the other Party's review and comment sufficiently in advance of such Party's filing or submission thereof (*provided* that such Party will have the right to redact or remove from such Regulatory Submissions any business sensitive or proprietary information of such Party, its Affiliates or Sublicensees contained in such Regulatory Submissions), and the submitting Party will make a good faith effort to incorporate comments received from the other Party into such Regulatory Submissions. In addition, the Regulatory Responsible Party will provide the other Party with written notice of each of the following events with regard to each Licensed Product, within a reasonable period of time (and prior to public disclosure of such event by the Regulatory Responsible Party) following the occurrence of: (i) the submission of any MAA filings of such Licensed Product to any Regulatory Authority, and (ii) receipt of Regulatory Approval or denial of any MAA for such Licensed Product (or inquiries from the applicable Regulatory Authority related to the MAA process).

6.5 Inspections. The Regulatory Responsible Party shall notify the other Party of any inspections of the Regulatory Responsible Party or any of its Affiliates, Sublicensees or subcontractors conducted by any Regulatory Authority and any related findings to the extent that such inspections relate to the activities conducted under this Agreement.

6.6 Cooperation. The Parties will cooperate with each other to achieve the regulatory objectives contemplated herein in a timely, accurate, and responsive manner. The non-Regulatory Responsible Party will assist the Regulatory Responsible Party, as is reasonably necessary in order for such Regulatory Responsible Party to obtain and maintain each applicable Marketing Authorization Application for the Licensed Products in the Regulatory Responsible Party's Territory, including in connection with the preparation, filing, and submission of all Regulatory Submissions by such Regulatory Responsible Party, including by providing to the Regulatory Responsible Party, as soon as reasonably practicable, such information and documentation that is in the other Party's possession and Control, to the extent such information and documentation is reasonably available and necessary or helpful for the Regulatory Responsible Party to prepare a response to an inquiry from a Regulatory Authority in the Regulatory Responsible Party's purview with respect to a Licensed Product.

6.7 Cost of Regulatory Activities. The Parties will share equally (50:50) all External Costs solely relating to regulatory activities associated with the conduct of Clinical Trials for the Licensed Products included within the Eligible Global Development Costs, and otherwise, the applicable Regulatory Responsible Party will be responsible for the costs incurred by each Party and its Affiliates in connection with the preparation or maintenance of Regulatory Submissions and Regulatory Approvals with respect to the Licensed Products in a given jurisdiction, including any filing fees.

6.8 Right of Reference. Subject to the rules of the relevant Regulatory Authority and the terms of this Agreement, each Party hereby grants to the other Party a "Right of Reference," as that term is defined in 21 C.F.R. § 314.3(b) (or any successor rule or analogous Applicable Law recognized outside of the United States) to, and a right to copy, access, and otherwise use, all information, data and other Know-How relating to the Licensed Compounds and Licensed Products that are included or referenced in any Regulatory Submission or Regulatory Approval Controlled by the grantor

Party during the Term, for the other Party's or its Affiliates' or Sublicensees' use in the Development and Commercialization of the Licensed Compounds and Licensed Products and to otherwise enable such Party to fulfill its obligations or exercise its rights with respect to Licensed Compounds and Licensed Products, in each case, in accordance with this Agreement. All such information and data contained in any such Regulatory Submissions or Regulatory Approvals will be considered Confidential Information of the grantor Party and subject to the terms of Article 12 (*Confidentiality*). If requested by the grantee Party, the grantor Party will provide a signed statement to this effect in accordance with 21 C.F.R. § 314.50(g)(3) (or any successor rule or analogous Applicable Law outside of the United States) to give effect to the intent of this Section 6.8 (*Right of Reference*).

6.9 Pharmacovigilance and Adverse Event Reporting. The Parties will cooperate with regard to the reporting and handling of safety information involving the Licensed Compounds and Licensed Products in accordance with Applicable Law, regulatory requirements, and regulations on pharmacovigilance and clinical safety. The Regulatory Responsible Party for the Licensed Products will be responsible for all processing of information related to any adverse events for such Licensed Product in the applicable jurisdiction, including any information regarding such adverse events that is received from a Third Party. Each Party will provide to the other Party in a timely manner the relevant safety information it receives (either directly or indirectly) related to the Licensed Compounds and Licensed Products. As soon as practicable after the Effective Date, the Parties will negotiate in good faith and enter into a Pharmacovigilance Agreement related to the Licensed Products, which will define the pharmacovigilance responsibilities of the Parties and include (a) safety data exchange procedures governing the exchange of information affecting the Licensed Products (*e.g.*, Serious Adverse Events, emerging safety issues) to enable each Party to comply with all of its legal and regulatory obligations related to such Licensed Product and (b) the terms of transfer of the global safety database from Fulcrum to Sanofi pursuant to Section 6.10 (*Global Safety Database*).

6.10 Global Safety Database. In accordance with the timeline set forth in the Pharmacovigilance Agreement, Fulcrum shall transfer the global safety database for the Licensed Products to Sanofi pursuant to the Pharmacovigilance Agreement. Thereafter, Sanofi will own and maintain the global safety database for the Licensed Products.

6.11 Recall, Withdrawal, or Field Alerts.

6.11.1 **Notification and Determination**. If any Governmental Authority threatens in writing or initiates any action to remove a Licensed Product from the market (in whole or in part), or if a Party determines that an event, incident or circumstance has occurred that may result in the need for a recall, withdrawal or field alert of a Licensed Product, then the Party initiating or receiving notice of such recall, withdrawal or field alert will notify the other Party of such communication immediately, but in no event later than [***] after receipt thereof. Notwithstanding the foregoing, in all cases the Regulatory Responsible Party for in a given jurisdiction will determine whether to initiate any recall, withdrawal, or field alert of the Licensed Products in such jurisdiction, including the scope of such recall or withdrawal (*e.g.*, a full or partial recall, or a temporary or permanent recall) or field alert. Before the Regulatory Responsible Party in a certain jurisdiction initiates a recall, withdrawal, or field alert for such Licensed Product in such jurisdiction, the Parties will use reasonable efforts to promptly meet and discuss in good faith the reasons therefor, *provided* that such discussions will not delay any action that such Regulatory Responsible Party reasonably believes should be taken in relation to any actual or potential recall, withdrawal, or field alert. In the event of any such recall, withdrawal, or field alert, the

Regulatory Responsible Party in the applicable jurisdiction will determine the necessary actions to be taken and will implement such action. Without limiting the foregoing, either Party will have the right to propose that a recall, withdrawal, or field alert for a Licensed Product should be initiated by such Party, but the Regulatory Responsible Party in the applicable jurisdiction will have the right to make the final decision as to whether or not to initiate the recall, withdrawal, or field alert. Notwithstanding any provision to the contrary set forth in this Agreement, if Fulcrum notifies Sanofi of a Manufacturing issue related to a Licensed Product prior to the Sanofi Territory Manufacturing Handover Date that Fulcrum reasonably believes could give rise to a recall, withdrawal, or field alert, then Sanofi, if it is the Regulatory Responsible Party for the applicable Licensed Product in the applicable jurisdiction, will initiate such recall, withdrawal, or field alert in accordance with Fulcrum's request. The Parties' rights and obligations under this Section 6.11 (*Recalls, Withdrawal or Field Alerts*) shall be subject to the terms of any applicable Pharmacovigilance Agreement entered into between the Parties. In the event of a conflict between the provisions of any Pharmacovigilance Agreement, and this Section 6.11 (*Recalls, Withdrawal or Field Alerts*), the provisions of such Pharmacovigilance Agreement shall govern with respect to the subject matter in this Section 6.11 (*Recalls, Withdrawal or Field Alerts*).

6.11.2 **Cost Allocation**. All costs directly associated with implementing a recall, withdrawal, or field alert with respect to a Licensed Product will be allocated between Fulcrum and Sanofi as follows:

(a) in the event, and to the extent, that the recall, withdrawal, or field alert arises as a result of a material breach of this Agreement or other gross negligence by a Party, then such Party will bear all such costs and expenses; and

(b) in all other cases, Fulcrum will be responsible for such costs and expenses for such Licensed Product in the Fulcrum Territory and Sanofi will be responsible for such costs and expenses for such Licensed Product in the Sanofi Territory.

6.12 Additional Activities. Notwithstanding anything contrary to this Agreement, the foregoing Sections 6.2.1 (*Correspondence*); 6.3 (*Regulatory Meetings*); 6.4 (*Regulatory Submissions*); and 6.8 (*Right of Reference*) shall not apply to any Additional Activity conducted as part of the Sanofi Independent Development Plan or Fulcrum Independent Development Plan.

ARTICLE 7
COMMERCIALIZATION

7.1 Commercialization Responsibilities for Licensed Product.

7.1.1 **Commercialization in the Fulcrum Territory**. Subject to alignment on a Joint Commercialization Strategy under Section 3.4.3(a) (*Specific Responsibilities of the JCC*), Section 3.1.5(d) (*Specific Responsibilities of the JSC*) and Section 3.8.2 (*Final Decision-Making Authority*), Fulcrum and its Affiliates will have sole control over and decision-making authority with respect to the Commercialization of the Licensed Products in the Fulcrum Territory, including, if applicable, whether to seek and maintain any Reimbursement Approval for the Licensed Products in the Fulcrum Territory, at its sole cost and expense.

7.1.2 **Commercialization in the Sanofi Territory**. Subject to alignment on a Joint Commercialization Strategy under Section 3.4.3(a) (*Specific Responsibilities of the JCC*), Section 3.1.5(d) (*Specific Responsibilities of the JSC*) and Section 3.8.2 (*Final Decision-Making Authority*) and Section 7.3 (*Sanofi Commercialization Diligence Obligations*), Sanofi and its Affiliates will have sole control over and decision-making authority with respect to the Commercialization of the Licensed Products in the Sanofi Territory, including whether to seek and maintain any Reimbursement Approval for the Licensed Products in the Sanofi Territory, at its sole cost and expense.

7.1.3 **Coordination of Commercialization Activities.** The Parties will coordinate global Commercialization activities with respect to Commercialization of the Licensed Products in each Party's Territory through the JCC, as expressly set forth in Section 3.4 (*Joint Commercialization Committee*) and this Article 7 (*Commercialization*).

7.2 Pricing. All decisions for the Licensed Products related to list price, targeted net pricing, sales-weighted average discounts and rebates, pricing strategy (including the approach to pricing with different types of accounts and plans, including types of discounts and rebates), and modifications to any of the foregoing, will be made by (a) Fulcrum in the Fulcrum Territory and (b) Sanofi in the Sanofi Territory.

7.3 Sanofi Commercialization Diligence Obligations. Following receipt of Regulatory Approval for a Licensed Product in a Sanofi Major Country, Sanofi will use Commercially Reasonable Efforts to [***]. Without limiting Fulcrum's rights under Section 14.2 (*Termination for Material Breach*) to terminate this Agreement in its entirety but notwithstanding any other provision in this Agreement, [***].

7.4 Standards of Conduct; Compliance. Each Party will perform, or will ensure that each of its Affiliates, Sublicensees, and subcontractors perform, all Commercialization activities in a professional and ethical business manner and in compliance with Applicable Law and applicable Professional Requirements.

7.5 Diversion. Neither Party nor its Affiliates will, and each Party will take reasonable measures to ensure that its Third Party Sublicensees and subcontractors do not, either directly or indirectly, promote, market, distribute, import, sell, or have sold any Licensed Product to any Third Party or to any address or internet protocol address or the like outside of such Party's Territory including via the Internet or mail order. Notwithstanding any provision to the contrary set forth in this Agreement, either Party will have the right to attend, or have its designees attend, conferences and meetings of congresses inside and outside of such Party's Territory, subject to this Section 7.5 (*Diversion*). As applicable, (a) in the case of Sanofi, in any country or jurisdiction outside of the Sanofi Territory or in the Sanofi Territory outside of the Field, and (b) in the case of Fulcrum, in any country or jurisdiction outside of the Fulcrum Territory:

7.5.1 such Party and its Affiliates will not engage, nor permit its Third Party Sublicensees and subcontractors to engage, in any advertising or promotional activities relating to any Licensed Product for use directed primarily to customers or other buyers or users of a Licensed Product located in any such country or jurisdiction;

7.5.2 such Party and its Affiliates will not solicit orders from any prospective purchaser located in any such country or jurisdiction;

7.5.3 such Party and its Affiliates may deliver, and shall cause its Third Party Sublicensees and subcontractors to deliver, Licensed Compounds or Licensed Products in such country or jurisdiction solely for Research and Development use as set forth in the Global Development Plan, and either the Sanofi Independent Development Plan or Fulcrum Independent Development Plan, as applicable;

7.5.4 such Party and its Affiliates will not, and will take reasonable measures to cause its Third Party Sublicensees and subcontractors to not, deliver or tender (or cause to be delivered or tendered) any Licensed Product to Third Parties for Commercialization in such country or jurisdiction; and

7.5.5 if either Party or its Affiliates or Sublicensees receive any order for any Licensed Product from a prospective purchaser located in any such country or jurisdiction, then such Party will immediately refer that order to the other Party or its designee and will not accept any such orders.

ARTICLE 8
MANUFACTURING

8.1 Responsibility.

8.1.1 **Fulcrum Manufacturing**. Fulcrum will have sole control over and decision-making authority with respect to, at its cost and expense, the Manufacture of (a) all supplies of the Licensed Compounds and Licensed Products required for Fulcrum's activities under the Global Development Plan and the Fulcrum Independent Development Plan (including the activities of Fulcrum's Affiliates and Sublicensees) and (b) all supplies of the Licensed Products for Commercialization purposes in the Fulcrum Territory. Additionally, and as set out more fully in the Global Development Plan, Fulcrum will develop drug substance and drug product processes for the Licensed Compounds and Licensed Products to enable Regulatory Approval from the EMA and other Regulatory Authorities in the Sanofi Territory and the Parties will share the costs of such activities in accordance with Section 5.7.1 (*Eligible Global Development Costs*).

8.1.2 **Sanofi Manufacturing**. From and after the date on which Sanofi's Manufacturing facility (or the Manufacturing facility of a CMO engaged by Sanofi) is qualified to Manufacture the Licensed Products (such date, the "**Sanofi Territory Manufacturing Handover Date**"), Sanofi will have sole responsibility for (subject to the Supply Agreement) control and decision-making authority with respect to, at its cost and expense, the Manufacture of (a) all supplies of the Licensed Compounds and Licensed Products required for Sanofi's activities under the Global Development Plan and the Sanofi Independent Development Activities and (b) all supplies of the Licensed Products for Commercialization purposes in the Sanofi Territory. A Manufacturing facility will be deemed "qualified" under the preceding sentence only if (i) such facility has been approved by the EMA for Manufacture of Licensed Compounds and Licensed Products, and (ii) with respect to the Manufacturing facility of a CMO, that supply and quality agreements have been executed between Sanofi and such CMO. For clarity, until the Sanofi Territory Manufacturing Handover Date, Sanofi (itself or through Third Parties) may also conduct CMC activities with respect to Licensed Compounds and Licensed Products, at its sole cost and expense, and shall include in the Sanofi Independent Development Plan the start and projected end dates for such activities (but for clarity, not the details of such activities).

8.2 Supply Agreement. If Sanofi needs any Licensed Compound or Licensed Product for (a) Development activities assigned to it under the Global Development Plan or the Sanofi Independent Development Plan prior to the Sanofi Territory Manufacturing Handover Date or, (b) Clinical Trials sponsored by Sanofi or its Affiliates under the Global Development Plan or the Sanofi Independent Development Plan following the Sanofi Territory Manufacturing Handover Date, or (c) Sanofi's Commercialization of Licensed Compounds or Licensed Products in the Sanofi Territory until the Sanofi Territory Manufacturing Handover Date, then the Parties will negotiate in good faith and enter into a supply agreement on reasonable and customary terms under which Fulcrum will Manufacture and supply Sanofi with any Licensed Compound and Licensed Product in bulk unlabeled form that is necessary for Sanofi to conduct its activities under the Sanofi Independent Development Plan and Global Development Plan (if any) and Commercialize Licensed Compounds and Licensed Products in the Sanofi Territory until the Sanofi Territory Manufacturing Handover Date (the "**Supply Agreement**"), and a related quality agreement, which agreements will govern the terms and conditions of the Manufacturing and supply of the Licensed Compounds or Licensed Products. The Supply Agreement will contain terms and conditions consistent with the principles set forth on **Schedule 8.2** (*Supply Agreement Term Sheet*).

8.3 Manufacturing Technology Transfer. At Sanofi's request, Fulcrum will, and will cause its Affiliates to, no later than [***] following such request, make available to Sanofi all Fulcrum Know-How and Fulcrum Materials (including analytical reference standards and raw data upon request of Sanofi) Controlled by Fulcrum or any of its Affiliates that are necessary or reasonably useful to enable Sanofi or its Affiliates to Manufacture (or have Manufactured) the Licensed Compounds and Licensed Products (such Fulcrum Know-How, the "**Fulcrum Manufacturing Technology**" and such activities, the "**Manufacturing Technology Transfer**"). Any materials provided by Fulcrum in connection with the transfer of the Fulcrum Manufacturing Technology will remain the sole property of Fulcrum, and Sanofi will (a) use such materials only in the fulfillment of obligations or exercise of rights under this Agreement, and (b) not use such Fulcrum Manufacturing Technology or materials or deliver the same to any Third Party, other than CMOs or permitted Sublicensees used in connection with Manufacturing, without Fulcrum's prior written consent, not to be unreasonably withheld, conditioned, or delayed. For purposes of the transfer of the Fulcrum Manufacturing Technology, the Parties may enter into a manufacturing technology transfer agreement, which will also provide for reasonable technical assistance and support by Fulcrum to Sanofi to enable Sanofi to Manufacture, or have Manufactured by a CMO engaged by Sanofi, the Licensed Compounds and Licensed Products ("**Manufacturing Technology Transfer Agreement**"). Fulcrum will (i) conduct the Manufacturing Technology Transfer at Fulcrum's sole cost and expense and (ii) provide support in connection with such Manufacturing Technology Transfer (including under any Manufacturing Technology Transfer Agreement), in each case ((i) and (ii)), at no cost to Sanofi for the [***] hours of activities and thereafter Fulcrum shall be reimbursed by Sanofi for all Internal Costs and External Costs it incurs in connection with such support within [***] of Sanofi's receipt of invoice from Fulcrum.

8.4 Manufacturing Audit Right by Sanofi. During normal business hours and upon reasonable written notice to Fulcrum, and without limiting Section 8.5 (*Observation by Sanofi*), (a) Fulcrum will, and will cause any of its CMOs to, provide Sanofi with the opportunity to inspect all records of Fulcrum or its Affiliates or CMOs (as applicable) that have been generated in connection with the Manufacture of Licensed Compounds and Licensed Products by or on behalf of Fulcrum, and (b) Fulcrum will, and will cause its Affiliates and CMOs to, provide Sanofi with the opportunity to visit the offices and laboratories of Fulcrum or any of its CMOs to discuss with Fulcrum (or such CMO) the Manufacture of Licensed Compounds and Licensed Products in further detail, in each case ((a) and (b)), for the sole purpose of conducting a technical manufacturing audit with respect

to the Manufacture of the Licensed Compounds and Licensed Products. In the event that the results of such audit reveal any deficiencies or other areas of remediation with respect to the Manufacture of Licensed Compounds or Licensed Products, then Sanofi shall notify Fulcrum in writing of the foregoing, and Fulcrum will (and, to the extent applicable, will cause any of its CMOs to) use diligent efforts to remediate any such deficiencies within [***] after Fulcrum's receipt of such notice. Notwithstanding the foregoing, any obligations that Fulcrum has under this Section 8.4 (*Manufacturing Audit Right by Sanofi*) with respect to any of its CMOs will be subject to Fulcrum's rights and obligations under the applicable agreement between Fulcrum and such CMOs; *provided*, that Fulcrum will use Commercially Reasonable Efforts to ensure that any such agreement executed after the Effective Date for the Manufacture of commercial supply of Licensed Compounds or Licensed Products permits Sanofi to exercise the audit rights set forth in this Section 8.4 (*Manufacturing Audit Right by Sanofi*).

8.5 Observation by Sanofi. In connection with the Manufacture of Licensed Products conducted by or on behalf of Fulcrum in accordance with Section 8.1.1 (*Fulcrum Manufacturing*), Fulcrum will provide Sanofi with the opportunity, upon Sanofi's reasonable request, for Sanofi's representatives to observe the Manufacturing processes and procedures for the Licensed Compounds and Licensed Products for the purpose of enabling Sanofi (or a CMO designated by Sanofi) to Manufacture the Licensed Compounds and Licensed Products pursuant to Section 8.3 (*Manufacturing Technology Transfer*). If Fulcrum utilizes a CMO for the Manufacture of any Licensed Compounds or Licensed Products, then Fulcrum will use commercially reasonable efforts to enable Sanofi to exercise its observational rights under this Section 8.5 (*Observation by Sanofi*) with respect to any Manufacturing activities for the Licensed Compounds and Licensed Products being conducted by such CMO.

ARTICLE 9
PAYMENTS

9.1 Upfront Payment. In consideration of the licenses, rights and privileges granted by Fulcrum to Sanofi hereunder and subject to the terms and conditions of this Agreement, Fulcrum will invoice Sanofi promptly on or after the Effective Date, and Sanofi will pay to Fulcrum no later than [***] following the receipt of such invoice, by wire transfer of immediately available funds, a one-time, non-refundable, non-creditable upfront payment of Eighty Million Dollars ($80,000,000) (the "**Upfront Payment**"), in accordance with wire instructions to be provided by Fulcrum to Sanofi in writing together with such invoice.

9.2 Milestone Payments.

9.2.1 **Regulatory Milestones**. No later than [***] after the earliest achievement of each regulatory milestone event set forth in Table 9.2.1 below for the first Licensed Product, Sanofi will notify Fulcrum thereof. Following Fulcrum's receipt of such notice from Sanofi, Fulcrum will invoice Sanofi for the corresponding regulatory milestone payment set forth in Table 9.2.1 (the regulatory milestone events set forth in Table 9.2.1, the "**Regulatory Milestone Events**" and the regulatory milestone payments set forth in Table 9.2.1, the "**Regulatory Milestone Payments**"), and Sanofi will pay to Fulcrum the applicable Regulatory Milestone Payment within [***] after receipt of such an undisputed invoice by wire transfer of immediately available funds. Each of the Regulatory Milestone Payments is payable only the first time the corresponding Regulatory Milestone Event is achieved, regardless of the number of times the applicable Regulatory Milestone Event is achieved. For clarity, no Regulatory Milestone Payment will be payable for subsequent or repeated achievements of the same Regulatory Milestone Event. If Sanofi achieves the

second or third Regulatory Milestone Event without the prior achievement of the first Regulatory Milestone Event, then Sanofi will pay to Fulcrum the first Regulatory Milestone Payment at the same time as Sanofi pays the applicable Regulatory Milestone Payment due upon achievement of such later Regulatory Milestone Event. For example, if Regulatory Milestone Event #1 in Table 9.2.1 has not been achieved at the time Regulatory Milestone Event #2 in Table 9.2.1 is achieved, then Sanofi will pay to Fulcrum the Regulatory Milestone Payment to be made with respect to such Regulatory Milestone Event #1 at the same time as Sanofi pays the Regulatory Milestone Payment due upon achievement of such Regulatory Milestone Event #2.

Table 9.2.1 –Regulatory Milestones

Regulatory Milestone Event	***Regulatory Milestone Payment (in U.S. Dollars)***
1. [***]	[***]
2. [***]	[***]
3. [***]	[***]

9.2.2 **Sales Milestones**. No later than [***] after each Calendar Year in which one or more sales milestone events set forth below is achieved based on the Net Sales for all Licensed Products, in the aggregate, in the Sanofi Territory, Sanofi will notify Fulcrum thereof in the last Royalty Report for such Calendar Year as described in Section 9.3.3(a) (*Royalty Report*). Following Fulcrum's receipt of such notice, Fulcrum will invoice Sanofi for the corresponding sales milestone payment, as set forth below (the sales milestone events set forth in Table 9.2.2, the "**Sales Milestone Events**" and the sales milestone payments set forth in Table 9.2.2, the "**Sales Milestone Payments**"), and Sanofi will pay the applicable Sales Milestone Payment within [***] after receipt of such an undisputed invoice by wire transfer of immediately available funds. Each of the Sales Milestone Payments is payable only the first time the corresponding Sales Milestone Event is achieved, regardless of the number of times the applicable Sales Milestone Event is achieved. For clarity, no Sales Milestone Payment will be payable for subsequent or repeated achievements of the same Sales Milestone Event. If in a given Calendar Year during the Term more than one of the Sales Milestone Events is achieved, then Sanofi will pay to Fulcrum a separate Sales Milestone Payment with respect to each such Sales Milestone Event that is achieved for the first time in such Calendar Year.

Table 9.2.2 – Sales Milestones

Sales Milestone Event	***Sales Milestone Payment (in U.S. Dollars)***
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

9.3 Royalties.

9.3.1 **Royalty Payments**. In consideration of the licenses, rights and privileges granted by Fulcrum to Sanofi hereunder and subject to the terms and conditions of this Agreement, Sanofi will pay to Fulcrum, on a Licensed Product-by-Licensed Product and country-by-country basis, royalties based on the Net Sales of a Licensed Product by Sanofi and its Affiliates and Sublicensees in the Sanofi Territory at the rates set forth in Table 9.3.1 below (the "**Royalties**") during the Royalty Term (the royalty payments made pursuant to this Section 9.3.1 (*Royalty Payments*), the "**Royalty Payments**," and the rates set forth in Table 9.3.1, the "**Royalty Rates**").

Table 9.3.1– Royalty Rates for the Licensed Products

Calendar Year Net Sales of a Licensed Product in the Sanofi Territory	***Royalty Rate***
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

By way of example only, if Sanofi receives [***] in Net Sales of a Licensed Product during a given Calendar Year, then Sanofi would owe Fulcrum a royalty of [***].

9.3.2 **Royalty Reduction**.

(a) **Patent Expiration Step-Down**. Subject to Section 9.3.2(d) (*Royalty Reductions Floor; Carry Forward*), on a Licensed Product-by-Licensed Product and country-by-country basis, if a Licensed Product is sold in a country in the Sanofi Territory during the applicable Royalty Term at a time when there is no Valid Claim of a Royalty Bearing Patent in such country, the Royalties payable by Sanofi with respect to the Net Sales of such Licensed Product in such country will be reduced by [***].

(b) **Generic Competition**. On a Licensed Product-by-Licensed Product and country-by-country basis, during the applicable Royalty Term for such Licensed Product, if in a Calendar Quarter following the first Calendar Quarter in which Generic Competition first occurs in such country (such first Calendar Quarter, the "**Launch Quarter**") the average quarterly Net Sales of such Licensed Product in such country decline by the percentage set forth in (a)-(c) in Table 9.3.2(b) below in this Section 9.3.2(b) (*Generic Competition*) relative to the average Net Sales of such Licensed Product in such country occurring during the [***] consecutive Calendar Quarters immediately preceding the Launch Quarter, then, thereafter, the then-applicable Royalty Rate payable with respect to annual Net Sales of such Licensed Product pursuant to this Section 9.3 (*Royalties*) in such country in the Sanofi Territory will be permanently reduced by the percentage described in Table 9.3.2(b) below in this Section 9.3.2(b) (*Generic Competition*):

Table 9.3.2(b)– Royalty Rates for Generic Competition

Decline in Annual Net Sales	***Royalty Reduction***
[***]	[***]
[***]	[***]
[***]	[***]

(c) **Royalty Stacking**.

(i) **By Sanofi**. If Sanofi or any of its Affiliates or Sublicensees obtain in an arms-length transaction a right or license under any Patent Rights or Know-How that are necessary to Exploit a Licensed Compound or Licensed Product that results in any payment(s) to such Third Party as a result of such right or license by Sanofi, its Affiliates or its Sublicensees, as applicable ("**Third Party Payments**"), then Sanofi may, subject to Section 9.3.2(d) (*Royalty Reductions Floor; Carry Forward*), deduct from any and all royalties under this Agreement that would otherwise have been due to Fulcrum an amount equal to [***] of the amount of any such Third Party Payments paid by Sanofi or any of its Affiliates or Sublicensees to such Third Party for such right or license or the exercise thereof.

(ii) **By Fulcrum**. Fulcrum will be solely responsible for all payment(s) owed or otherwise arising from its Existing Third Party IP Agreements. All such payments shall be made promptly by Fulcrum in accordance with the terms of the applicable Existing Third Party IP Agreement.

(d) **Royalty Reductions Floor; Carry Forward**. Notwithstanding the reductions set forth in this Section 9.3.2 (*Royalty Reduction*), in no event will the Royalties due to Fulcrum for a Licensed Product in a country in the Sanofi Territory in any given Calendar Quarter during the Royalty Term for such Licensed Product in such country be reduced under this Section 9.3.2 (*Royalty Reduction*) by more than [***] of the amount that otherwise would have been due and payable to Fulcrum in such Calendar Quarter for such Licensed Product in such country but for the reductions set forth in this Section 9.3.2 (*Royalty Reduction*), Sanofi may carry forward any such reductions permitted under this Section 9.3.2 (*Royalty Reduction*) that are incurred or accrued in a Calendar Quarter but are not applied against royalties due to Fulcrum in such Calendar Quarter as a result of the foregoing floor and apply such amounts against royalties due to Fulcrum in any subsequent Calendar Quarter (subject to the minimum floor set forth in this Section 9.3.2(d) (*Royalty Reductions Floor; Carry Forward*)) until the amount of such reduction has been fully applied against royalties due to Fulcrum.

9.3.3 **Royalty Payments and Reports**.

(a) **Royalty Report**. Commencing with the Calendar Quarter during which the First Commercial Sale of a Licensed Product is made anywhere in the Sanofi Territory, within [***] after the end of each Calendar Quarter, Sanofi will provide to Fulcrum a written report (each, a "**Royalty Report**") setting forth in reasonable detail: (a) the aggregate Net Sales of the Licensed Products sold by Sanofi or its Affiliates or Sublicensees in the Sanofi Territory in such Calendar Quarter; (b) all deductions and reductions used to determine the Net Sales of the Licensed Products for such Calendar Quarter or the Royalties payable with respect to the Licensed Products for such Calendar Quarter, including any reduction pursuant to Section 9.3.2 (*Royalty Reduction*); (c) the exchange rates used to calculate the Royalties payable in U.S. Dollars; and (d) any withholding taxes required to be made from such Royalties. The Parties will seek to resolve any questions or issues related to a Royalty Report within [***] following receipt by Fulcrum of each Royalty Report.

Sanofi will provide such Royalty Reports for so long as any Royalty Term remains in effect for a given Licensed Product.

(b) **Royalty Payments**. The information contained in each Royalty Report will be considered Confidential Information of Sanofi. Following Fulcrum's receipt of each Royalty Report, Fulcrum will invoice Sanofi for the royalty amounts due for such Calendar Quarter and Sanofi will pay to Fulcrum such amounts, less any applicable withholding tax that is required by Applicable Law in accordance with Section 9.11.2 (*Withholding Tax*), within [***] after receipt of such an undisputed invoice in immediately available funds by wire transfer, in accordance with wire instructions to be provided by Fulcrum to Sanofi together with such invoice.

9.4 Other Amounts Payable. With respect to any amounts owed under this Agreement by one Party to the other for which no other invoicing and payment procedure is specified hereunder, within [***] after the end of each Calendar Quarter, each Party will provide an invoice, together with reasonable supporting documentation, to the other Party for such amounts owed in respect of such Calendar Quarter. The owing Party will pay any undisputed invoiced amounts within [***] after receipt of the invoice, and any disputed amounts owed by a Party will be paid within [***] following resolution of the dispute.

9.5 Invoices. Notwithstanding any provision to the contrary in this Agreement, Fulcrum will deliver an invoice to Sanofi for all payments owed by Sanofi to Fulcrum under this Agreement. Except where a different timeframe is expressly provided in another section of this Agreement, Sanofi will make all payments owed to Fulcrum within [***] after the date on which Sanofi receives an undisputed invoice for such owed amount.

9.6 General Right to Reconcile Payments. To the extent permitted under Applicable Law, each Party will have the right to offset any amount owed to it by the other Party under or in connection with this Agreement which obligation is not being disputed by such owing Party in good faith, including in connection with any breach or indemnification obligation by such owing Party, against any payments owed by such Party to the other Party under this Agreement. Such offsets will be in addition to any other rights or remedies available under this Agreement or Applicable Law.

9.7 Financial Records and Audits.

9.7.1 **Financial Records**. Each Party will, and will require its Affiliates, Sublicensees and subcontractors to, maintain complete, true and accurate records in accordance with such Party's Accounting Standards in relation to this Agreement, including (as applicable) any Eligible Global Development Costs, Royalties, Milestone Payments and Net Sales. Each Party will keep such records for at least [***] following the Calendar Year to which they pertain or for such longer period of time as required under any Applicable Law.

9.7.2 **Audit Rights**. During the Term, upon at least [***] prior written notice, each Party agrees to permit such records to be open during regular business hours for examination by an independent, nationally-recognized certified public accountant selected by the auditing Party at the auditing Party's expense and reasonably acceptable to the audited Party (the "**Auditor**") for the sole purpose of verifying the accuracy of the financial reports furnished by the audited Party pursuant to this Agreement or of any payments made, or required to be made, by the audited Party pursuant to this Section 9.7 (*Financial Records and Audits*); *provided* that (a) the Auditor is subject to written obligations of confidentiality and non-use applicable to each Party's Confidential Information that are at least as stringent as those

set forth in Article 12 (*Confidentiality*) and that limit the disclosure and use of such information by such Auditor to authorized representatives of the Parties and the purposes germane to this Section 9.7 (*Financial Records and Audits*), except that the term of such obligations will be customary for such recipient of Confidential Information, (b) such audit right will not apply to records beyond [***] from the end of the Calendar Year to which they pertain, and (c) such audit will not be (i) performed more frequently than once per [***] period, or (ii) repeated for any Calendar Year or with respect to the same set of records (in each case, unless a material discrepancy with respect to such records is discovered during a prior audit). The Auditor will report to the auditing Party only whether the particular amount being audited was accurate and, if not, the amount of any discrepancy and a reasonable summary of the reason for such discrepancy, and the Auditor will not report any other information to the auditing Party. The auditing Party will treat the results of the Auditor's review of the audited Party's records as Confidential Information of the audited Party subject to the terms of Article 12 (*Confidentiality*). In the event such audit leads to the discovery of a discrepancy to the auditing Party's detriment, the audited Party will pay any amounts shown to be owed to the auditing Party but unpaid within [***] after the Auditor's report. If such examination of records reveals any overpayment by a Party, then the other Party will credit the amount overpaid against future amounts due to the other Party by the overpaying Party. The auditing Party will bear the full cost of such audit unless such audit reveals an underpayment by the audited Party of more than [***] of the amount actually due for the time period being audited, in which case the audited Party will reimburse the auditing Party for the reasonable audit fees for such examination. Any undisputed overpayments by the audited Party revealed by an examination will be paid by the auditing Party within [***] of the auditing Party's receipt of the applicable report.

9.8 Accounting Standards. If a Party changes its general accounting principles from its then-current Accounting Standard (*e.g.*, from GAAP to IFRS) at any time during the Term, then at least [***] prior to adopting such change in principles, such Party will provide written notice to the other Party of such change. A Party may not change its general accounting principles to any accounting standard other than GAAP or IFRS without the prior written approval of the other Party.

9.9 Method of Payment; Exchange Rate. All payments to be made by Sanofi to Fulcrum or Fulcrum to Sanofi under this Agreement will be made in Dollars by electronic funds transfer in immediately available funds to a bank account designated in writing by Fulcrum or Sanofi, as applicable. Conversion of Net Sales recorded in local currencies will be converted to Dollars in a manner consistent with the Accounting Standard and the normal practices used by the Party owing or making a payment under this Agreement to prepare its audited financial statements.

9.10 Blocked Payments. If by reason of Applicable Law in any country or jurisdiction, it becomes impossible or illegal for a Party to transfer, or have transferred on its behalf, payments owed the other Party hereunder, then such Party will promptly notify the other Party of the conditions preventing such transfer and use reasonable efforts to deposit such payments in Dollars. If, after using reasonable efforts, such Party is not able to deposit such payments in Dollars, then such payments will be deposited in local currency in the relevant country to the credit of the other Party in a recognized banking institution designated by the other Party or, if none is designated by the other Party within a period of [***], in a recognized banking institution selected by the transferring Party, as the case may be, and identified in a written notice given to the other Party.

9.11 Taxes.

9.11.1 **Taxes on Income**. Each Party will be solely responsible for the payment of any and all income Taxes levied on account of all payments it receives under this Agreement.

9.11.2 **Withholding Tax**. Any and all payments made pursuant to this Agreement will be paid without deduction or withholding for any Taxes, except as required by Applicable Law. To the extent a Party is required by Applicable Law to deduct or withhold Taxes on any payment to the other Party (the "**Withheld Amount**"), such Party will remit such Withheld Amount to the proper Governmental Authority in a timely manner and promptly transmit to the other Party an official Tax certificate or other evidence of any withholding sufficient to enable the other Party to claim available credits for such Withheld Amount. The withholding Party will have the right to deduct such Withheld Amount from payment due to the other Party. For the avoidance of doubt, to the extent such Withheld Amount is so withheld and remitted in accordance with this Section 9.11.2 (*Withholding Tax*), such Withheld Amount will be treated for all purposes of this Agreement as having been paid to the other Party.

9.11.3 **Tax Cooperation**. The Parties agree to cooperate with one another in accordance with Applicable Law and use reasonable efforts to mitigate or reduce Tax withholding or similar obligations in respect of payments made by each Party to the other Party under this Agreement. Without limiting the generality of the foregoing, each Party will provide the other with any Tax forms and other information that may be reasonably necessary to reduce withholding based on an applicable treaty or otherwise, including a properly completed Internal Revenue Service ("**IRS**") Form W-9 or appropriate IRS Form W-8, as applicable, before a payment is made. If any Tax form or other information a Party previously delivered expires or becomes obsolete or inaccurate in any respect, such Party will provide the other Party with an updated version of such form or certification or promptly notify the other Party in writing of its legal inability to do so. Each Party will provide the other Party with reasonable assistance to enable the recovery, as permitted by Applicable Law, of withholding Taxes or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding Tax.

9.11.4 **Changes in Domicile**. Notwithstanding any provision to the contrary in this Agreement, including Section 9.11.2 (*Withholding Tax*), if as a result of a Party assigning, transferring, or conveying rights under this Agreement to an Affiliate or changing its domicile, additional Taxes become due that would not otherwise have been due hereunder with respect to payments under this Agreement, then such Party will be responsible for all such additional withholding Taxes.

9.12 Late Payments; Disputed Payments. Any undisputed payments or portions thereof due hereunder that are not paid on or before the date such payments are due under this Agreement will bear interest from the due date until the date of payment at a per-annum rate equal to the lesser of: (a) [***] above the [***] Secured Overnight Financing Rate (SOFR) as published by the Federal Reserve Bank of New York; or (b) the maximum rate permitted by Applicable Law. If a Party disputes an invoice or other payment obligation under this Agreement, then such Party will timely pay the undisputed amount of the invoice or other payment obligation, and the Parties will resolve such dispute in accordance with Article 15 (*Dispute Resolution; Governing Law*).

ARTICLE 10
INTELLECTUAL PROPERTY

10.1 Inventions.

10.1.1 **Ownership of Background Technology**. As between the Parties, each Party will retain all of its rights, title and interests in and to all Patent Rights, Know-How and other intellectual property rights that are Controlled by such Party or its Affiliates prior to the Effective Date or are otherwise conceived, discovered, developed, invented, created or otherwise made or acquired by such Party or its Affiliates outside the performance of activities under this Agreement (such Patent Rights with respect to a Party, "**Background Patents**," such Know-How with respect to a Party, "**Background Know-How**," and the Background Patents and Background Know-How collectively, "**Background Technology**"), subject to any rights or licenses expressly granted by such Party to the other Party under this Agreement.

10.1.2 **Ownership of Foreground Intellectual Property**. As between the Parties, subject to any rights or licenses expressly granted by one Party to the other Party under this Agreement, ownership of all Collaboration Technology will be as follows:

(a) Fulcrum is and will be the sole owner of all Collaboration Patent Rights solely invented by or on behalf of Fulcrum or its Affiliates in the performance of activities under this Agreement. Fulcrum is and will be the sole owner of all other Collaboration Know-How solely conceived, discovered, developed, invented or otherwise made by Fulcrum or its Affiliates in the performance of activities under this Agreement. With respect to any Collaboration Know-How conceived, discovered, developed, invented or otherwise made by Fulcrum's Sublicensees or Collaboration Patent Rights invented by Fulcrum's Sublicensees, Fulcrum or its Affiliates will have and maintain sufficient rights, if any, under such Collaboration Know-How and Collaboration Patent Rights, so that such are Fulcrum Know-How or Fulcrum Patent Rights, as applicable, under this Agreement.

(b) Sanofi is and will be the sole owner of all Collaboration Patent Rights solely invented by or on behalf of Sanofi or its Affiliates in the performance of activities under this Agreement. Sanofi is and will be the sole owner of all other Collaboration Know-How solely conceived, discovered, developed, invented or otherwise made by Sanofi or its Affiliates in the performance of activities under this Agreement. With respect to any Collaboration Know-How conceived, discovered, developed, invented or otherwise made by Sanofi's Sublicensees or Collaboration Patent Rights invented by Sanofi's Sublicensees, Sanofi or its Affiliates will have and maintain sufficient rights, if any, under such Collaboration Know-How and Collaboration Patent Rights, so that such are Sanofi Know-How or Sanofi Patent Rights, as applicable, under this Agreement.

(c) Fulcrum and Sanofi will jointly own all Joint Collaboration Technology on an equal and undivided basis.

10.1.3 **Disclosure; Inventorship**.

(a) **Invention Disclosure**. Each Party will promptly disclose to the other Party all potential Inventions within the Collaboration Technology, in each case, no later

than [***] after the applicable Party's intellectual property department receives notice of such potential Invention and in any event as soon as practicable prior to any intended public disclosure of such potential Invention under Section 12.5 (*Joint Publication Strategy*) and prior to the filing of a patent application thereon. Each Party will also promptly respond to reasonable requests from the other Party for additional information relating thereto.

(b) **Inventions by a Party**. Inventorship for Inventions and discoveries (including Know-How) first invented or developed during the course of the performance of activities under this Agreement will be determined in accordance with United States patent law.

(c) **CREATE Act**. Notwithstanding any provision to the contrary set forth in this Agreement, neither Party may invoke the Cooperative Research and Technology Enhancement Act, 35 U.S.C. § 102(c) (the "**CREATE Act**") when exercising its rights under this Agreement without the prior written approval of the other Party. If a Party intends to invoke the CREATE Act, then it will notify the other Party and if agreed by the Parties the other Party will cooperate and coordinate its activities with such Party with respect to any filings or other activities in support thereof. The Parties acknowledge and agree that this Agreement is a "joint research agreement" as defined in the CREATE Act.

10.1.4 **Employee Assignment**. Each Party and its Affiliates will, and will cause its Sublicensees and subcontractors to, enter into an agreement or employment policy with each of its employees performing activities under this Agreement that (a) compels prompt disclosure to such Party (or its Sublicensee or its subcontractor, as applicable) of all Collaboration Know-How and Collaboration Patent Rights discovered or developed, invented, or filed by such employee during any performance under this Agreement; and (b) automatically assigns to such Party (or its Sublicensee or its subcontractor, as applicable) all rights, title, and interests in and to all Collaboration Know-How and Collaboration Patent Rights, and requires each employee to execute all documents and take such other actions as may be necessary to effectuate such assignment. In addition, each Party shall require its employees and contractors who are inventors on any such Collaboration Know-How or Collaboration Patent Rights to cooperate and provide assistance to its employer or its Affiliate in relevant intellectual property-related matters, including by executing all appropriate documents, cooperating in discovery and, if legally required to continue any such enforcement activities, joining as a party to any action or providing a power of attorney solely for such purpose.

10.1.5 **Practice Under and Other Use of Joint Collaboration Technology**. Subject to the rights granted under and the restrictions set forth in this Agreement (including the licenses granted under Article 2 (*Licenses*) and the restrictions set forth in Section 2.7 (*Exclusivity*)), each Party will be entitled to the free use and enjoyment of all Joint Collaboration Technology, and neither Party will have any obligation to account to the other Party for profits, or to obtain any approval of the other Party to license, assign, or otherwise exploit any Joint Collaboration Technology by reason of joint ownership thereof. Each Party hereby waives, and agrees to waive, any right it may have under the Applicable Law of any jurisdiction to require any such approval or accounting. To the extent any further consent is required to enable a Party to so license or exploit its interest in the Joint Collaboration Technology, the other Party will grant consent promptly upon request. Without limitation, each Party will cooperate with the other Party if the Parties determine

to apply for U.S. or foreign patent protection for any Joint Collaboration Technology and will obtain the cooperation of the individual inventors of any such Joint Collaboration Technology.

10.2 Patent Prosecution.

10.2.1 **Fulcrum Patent Rights and Joint Collaboration Patent Rights**.

(a) **Right to Prosecute**. As between the Parties, Fulcrum will have the first right to control the Patent Prosecution of all Collaboration Patent Rights in the Fulcrum Territory and the sole right, in its sole discretion, to control the Patent Prosecution of all Fulcrum Patent Rights in the Fulcrum Territory (the "**Fulcrum Prosecuted Patent Rights**"). Fulcrum will be responsible for [***] of the costs and expenses incurred with respect to the Patent Prosecution of such Patent Rights in the Fulcrum Territory.

(b) **Review and Consult**. Fulcrum will consult with Sanofi and keep Sanofi reasonably informed regarding the Patent Prosecution of the Fulcrum Prosecuted Patent Rights and will provide Sanofi with all material, substantive correspondence received from any patent authority in the Fulcrum Territory in connection therewith no later than [***] after receipt thereof. In addition, Fulcrum will provide Sanofi with drafts of proposed substantive filings in the Fulcrum Territory and correspondence to any patent authority in the Fulcrum Territory in connection with the Patent Prosecution of the Fulcrum Prosecuted Patent Rights for Sanofi's review and comment at least [***] prior to the submission of such proposed filings and correspondence, which comments (if any) Sanofi must provide no later than [***] after receipt of the applicable filing or correspondence. Fulcrum will consider in good faith Sanofi's reasonable comments on the Patent Prosecution of the Fulcrum Prosecuted Patent Rights in the Fulcrum Territory, but Fulcrum will have final decision-making authority regarding Patent Prosecution of such Patent Rights under this Section 10.2.1(b) (*Review and Consult*). Sanofi will be responsible for [***] of the costs and expenses incurred with respect to its review and consultation under this Section 10.2.1(b) (*Review and Consult*).

(c) **Abandonment**. If, at any time during the Term, Fulcrum decides to cease the Patent Prosecution of a particular Collaboration Patent Right solely or jointly owned by Sanofi in the Fulcrum Territory, Fulcrum will notify Sanofi of such decision at least [***] prior to the date that such applicable Collaboration Patent Right will become abandoned, and then, unless Fulcrum has a Strategic Business Rationale for ceasing such Patent Prosecution, Sanofi may, upon written notice to Fulcrum, assume the Patent Prosecution of any such Patent Right at Sanofi's sole cost and expense.

10.2.2 **Sanofi Patent Rights**.

(a) **Right to Prosecute**. As between the Parties, Sanofi will have the first right, in its sole discretion, to control the Patent Prosecution of all Fulcrum Patent Rights and Collaboration Patent Rights in the Sanofi Territory (the "**Sanofi Prosecuted Patent Rights**"). Sanofi will be responsible for [***] of the costs and expenses incurred with respect to the Patent Prosecution of such Patent Rights.

(b) **Review and Consult**. Sanofi will consult with Fulcrum and keep Fulcrum reasonably informed regarding the Patent Prosecution of the Sanofi Prosecuted Patent Rights and will provide Fulcrum with all material, substantive correspondence received from the European Patent Office ("**EPO**") in connection therewith no later than [***] after receipt thereof. In addition, Sanofi will provide Fulcrum with drafts of all proposed substantive filings and correspondence to the EPO in connection with the Patent Prosecution of the Sanofi Prosecuted Patent Rights for Fulcrum's review and comment at least [***] prior to the submission of such proposed filings and correspondence, which comments (if any) Fulcrum must provide no later than [***] after receipt of the applicable filing or correspondence. Sanofi will consider in good faith Fulcrum's reasonable comments on the Patent Prosecution of the Sanofi Prosecuted Patent Rights, but Sanofi will have final decision-making authority regarding Patent Prosecution of such Patent Rights under this Section 10.2.2(b) (*Review and Consult*). Fulcrum will be responsible for [***] of the costs and expenses incurred with respect to its review and consultation under this Section 10.2.2(b) (*Review and Consult*).

(c) **Abandonment**. If, at any time during the Term, Sanofi ceases the Patent Prosecution of a particular Sanofi Prosecuted Patent Right solely or jointly owned by Fulcrum in the Sanofi Territory, then, Sanofi will notify Fulcrum of such decision at least [***] prior to the date on which such Patent Right will become abandoned, and then, unless Sanofi has a Strategic Business Rationale for ceasing such Patent Prosecution, Fulcrum may, upon written notice to Sanofi, assume the Patent Prosecution of any such Patent Right at Fulcrum's sole cost and expense.

10.2.3 **First Priority and PCT Applications.** Notwithstanding the foregoing, following discussion and coordination by the Parties, the Parties will jointly control the filing of any first priority application (i.e., a U.S. provisional application or other patent application establishing the first priority date of an Invention) or international patent applications under the Patent Cooperation Treaty claiming a Collaboration Patent Right.

10.3 Enforcement Against Third Party Infringement or Misappropriation.

10.3.1 **Notice of Infringement or Misappropriation**. Each Party will promptly notify the other of any apparent, threatened, or actual Third Party infringement, misappropriation or other violation of any potentially enforceable intellectual property right within the Fulcrum Technology or the Collaboration Technology (*e.g.*, by reason of the making, using, offering to sell, selling, or importing of a compound, product, method, or process that would be competitive with a Licensed Product in the Field) (a "**Competitive Infringement**") of which it becomes aware. The Parties will promptly discuss the Competitive Infringement and the course of action to be taken in connection therewith, including a coordinated plan for all related jurisdictions, claims, and counterclaims.

10.3.2 **Enforcement in the Sanofi Territory.** Subject to the terms of any applicable license pursuant to which Fulcrum Controls any Patent Right or Know-How included within the Fulcrum Patent Rights or Fulcrum Know-How, as between the Parties, Sanofi will have the first right, but not the obligation, to bring and control any legal action (including settlements thereof) or take such other actions as it deems appropriate in connection with any Competitive Infringement in the Sanofi Territory; *provided* that Fulcrum will be entitled to attend any material and substantive meetings, hearings, or other proceedings related to such infringement or misappropriation suit (together with its own counsel, at its

own expense). If Sanofi fails to timely abate any such Competitive Infringement or initiate a suit or take other action to abate any such Competitive Infringement without a Strategic Business Rationale, Fulcrum will have the second right, but not the obligation, to attempt to resolve such Competitive Infringement if such Competitive Infringement relates to any intellectual property right within the Fulcrum Technology or any Collaboration Technology that is solely or jointly owned by Fulcrum, at its own expense, including the filing of an infringement or misappropriation suit, as applicable, to enforce the applicable Patent Rights or Know-How using counsel of its own choice. Any recovery (including any settlement) received as a result of any action under this Section 10.3.2 (*Enforcement in the Sanofi Territory*) will be allocated in the following order: (a) first, to reimburse Sanofi for the costs and expenses (including attorneys' and professional fees) that Sanofi incurred in connection with such action, to the extent not previously reimbursed; (b) second, to reimburse Fulcrum, where it joins a legal action as provided under Section 10.5.4 (*Cooperation*), for the reasonable and documented costs and expenses (including attorneys' and professional fees) that Fulcrum incurred in connection with such action, to the extent not previously reimbursed; and (c) third, any remaining amounts will be retained by Sanofi (*provided*, that such remainder shall be subject to royalty payments to Fulcrum as if such remainder constituted Net Sales under this Agreement). Fulcrum will have the right to consult and comment upon any such enforcement action in the Sanofi Territory in accordance with Section 10.5.4 (*Cooperation*).

10.3.3 **Enforcement in the Fulcrum Territory**. As between the Parties, Fulcrum will have the sole right, but not the obligation, to bring and control any legal action (including settlements thereof) or take such other actions as it deems appropriate in connection with any Competitive Infringement in the Fulcrum Territory. Any recovery (including any settlement) received as a result of any action under this Section 10.3.3 (*Enforcement in the Fulcrum Territory*) will be allocated in the following order: (a) first, to reimburse Fulcrum for the costs and expenses (including attorneys' and professional fees) that Fulcrum incurred in connection with such action, to the extent not previously reimbursed; (b) second, to reimburse Sanofi, where it joins a legal action as provided under Section 10.5.4 (*Cooperation*), for the reasonable and documented costs and expenses (including attorneys' and professional fees) that Sanofi incurred in connection with such action, to the extent not previously reimbursed; and (c) third, any remaining amounts will be retained by Fulcrum. Sanofi will have the right to consult and comment upon any such enforcement action in the Fulcrum Territory in accordance with Section 10.5.4 (*Cooperation*).

10.3.4 **Cooperation**. Subject to Section 10.3.2 (*Enforcement in the Sanofi Territory*) and Section 10.3.3 (*Enforcement in the Fulcrum Territory*), the Party that is responsible for the applicable enforcement action (the "**Enforcing Party**") will keep the other Party (the "**Non-Enforcing Party**") reasonably informed of the status and progress of such enforcement action. The Enforcing Party will reasonably consult with the Non-Enforcing Party, including using reasonable efforts to take the Non-Enforcing Party's reasonable and timely comments into good faith consideration with respect to such enforcement action, including the infringement or claim construction of any claim in the applicable Patent Right. The Non-Enforcing Party will also provide reasonable assistance in connection with such enforcement action, including by executing reasonably appropriate documents, cooperating in discovery and joining as a party to the action if required. Each Party will bear its own costs and expenses under this Section 10.3 (*Enforcement Against Third Party Infringement or Misappropriation*).

10.4 Defense of Third Party Patent Challenges. Each Party will notify the other Party in writing promptly upon becoming aware of an actual or threatened Patent Challenge by a Third Party of any Fulcrum Patent Right or Collaboration Patent Right (each, a "**Third Party Patent Challenge**").

10.4.1 **Defense of Third Party Patent Challenges in the Sanofi Territory**. Subject to the terms of Section 10.4.3 (*Cooperation; Procedures*), Sanofi will have the first right, but not the obligation, to control the defense of any Third Party Patent Challenge relating to a Fulcrum Patent Right, Sanofi Patent Right or Collaboration Patent Right in the Sanofi Territory and to compromise, litigate, settle, or otherwise dispose of any such challenge, in each case at its own expense using counsel of its own choice; *provided* that Fulcrum will be entitled to attend any material and substantive meetings, hearings, or other proceedings related to such Third Party Patent Challenge (together with its own counsel, at its own expense) and to review and comment on all substantive documents related to such Third Party Patent Challenge. If Sanofi fails to initiate or continue the defense of such Third Party Patent Challenge of a Sanofi Prosecuted Patent Right solely or jointly owned by Fulcrum without a Strategic Business Rationale within [***] after the notice provided under Section 10.4 (*Defense of Third Party Patent Challenges*), or otherwise abandons or elects not to continue any such defense once initiated without a Strategic Business Rationale, then Fulcrum will have the second right, but not the obligation, to control the defense of such Third Party Patent Challenge at its own expense using counsel of its own choice.

10.4.2 **Defense of Third Party Patent Challenges in the Fulcrum Territory**. Subject to the terms of Section 10.4.3 (*Cooperation; Procedures*), Fulcrum will have the first right, but not the obligation, to control the defense of any Third Party Patent Challenge relating to a Fulcrum Patent Right or Collaboration Patent Right in the Fulcrum Territory and to compromise, litigate, settle, or otherwise dispose of any such challenge, in each case at its own expense using counsel of its own choice; *provided* that Sanofi will be entitled to attend any material and substantive meetings, hearings, or other proceedings related to such Third Party Patent Challenge (together with its own counsel, at its own expense) and to review and comment on all substantive documents related to such Third Party Patent Challenge. If Fulcrum fails to initiate or continue the defense of such Third Party Patent Challenge of a Collaboration Patent Right solely or jointly owned by Sanofi without a Strategic Business Rationale within [***] after the notice provided under Section 10.4 (*Defense of Third Party Patent Challenges*), or otherwise abandons or elects not to continue any such defense once initiated without a reasonable reason, then Sanofi will have the second right, but not the obligation, to control the defense of such Third Party Patent Challenge at its own expense using counsel of its own choice.

10.4.3 **Cooperation; Procedures**. At the request and expense of the Party controlling the defense of any Third Party Patent Challenge under this Section 10.4 (*Defense of Third Party Patent Challenges*), the other Party will provide reasonable assistance and cooperation in any such action. In addition, the Party controlling the defense of any Third Party Patent Challenge under this Section 10.4 (*Defense of Third Party Patent Challenges*) will provide the other Party with copies of all material and substantive pleadings and other documents to be filed with the court and will consider reasonable and timely input from the other Party during the course of the action. Sanofi may not settle any action or proceeding brought or defended under this Section 10.4 (*Defense of Third Party Patent Challenges*) or knowingly take any other action in the course thereof without Fulcrum's prior consent, unless such action or proceeding solely concerns the Sanofi Patent Rights, such consent not to be unreasonably withheld, delayed or conditioned. Fulcrum may not settle any action or proceeding brought or defended under this Section 10.4 (*Defense of Third Party Patent Challenges*) or

knowingly take any other action in the course thereof without Sanofi's prior consent with respect to the Sanofi Territory, such consent not to be unreasonably withheld, delayed or conditioned. The Parties will reasonably assist each other and cooperate with each other, at their own expense, in any such investigation, pre-litigation preparation, or litigation to ensure that there is an aligned global litigation strategy.

10.5 Third Party Infringement Claims.

10.5.1 **Notification.** Each Party will promptly notify the other Party of any claim alleging that the Research, Development, Manufacture, Commercialization or other Exploitation of the Licensed Compounds or Licensed Products in the Territory infringes, misappropriates or otherwise violates any Patent Rights, Know-How or other intellectual property rights of any Third Party ("**Third Party Infringement**"). The Parties will promptly discuss the Third Party Infringement and the course of action to be taken in connection therewith, including a coordinated plan for all related jurisdictions, claims, and counterclaims.

10.5.2 **Right to Defend in the Sanofi Territory.** Sanofi will have the sole right, but not the obligation, to defend, and take other actions (including to settle), with respect to any such claim of Third Party Infringement in the Sanofi Territory, at Sanofi's sole discretion, and Fulcrum will have the right to be represented in any such action by counsel of its own choice. Any recovery (including any settlement) received as a result of any action under this Section 10.5.2 (*Right to Defend in the Sanofi Territory)* will be allocated in the following order: (a) first, to reimburse Sanofi for the costs and expenses (including attorneys' and professional fees) that Sanofi incurred in connection with such action, to the extent not previously reimbursed; (b) second, to reimburse Fulcrum, where it joins a legal action as provided under this Section 10.5.2 (*Right to Defend in the Sanofi Territory*) or Section 10.5.4 (*Cooperation*), for the reasonable and documented costs and expenses (including attorneys' and professional fees) that Fulcrum incurred in connection with such action, to the extent not previously reimbursed; and (c) third, any remaining amounts will be retained by Sanofi.

10.5.3 **Right to Defend in the Fulcrum Territory.** Fulcrum will have the sole right, but not the obligation, to defend, and take other actions (including to settle), with respect to any such claim of Third Party Infringement in the Fulcrum Territory, at Fulcrum's sole discretion, and Sanofi will have the right to be represented in any such action by counsel of its own choice. Any recovery (including any settlement) received as a result of any action under this Section 10.5.3 (*Right to Defend in the Fulcrum Territory*) will be allocated in the following order: (a) first, to reimburse Fulcrum for the costs and expenses (including attorneys' and professional fees) that Fulcrum incurred in connection with such action, to the extent not previously reimbursed; (b) second, to reimburse Sanofi, where it joins a legal action as provided under this Section 10.5.3 (*Right to Defend in the Fulcrum Territory*) or Section 10.5.4 (*Cooperation*), for the reasonable and documented costs and expenses (including attorneys' and professional fees) that Sanofi incurred in connection with such action, to the extent not previously reimbursed; and (c) third, any remaining amounts will be retained by Fulcrum.

10.5.4 **Cooperation**. Subject to Section 10.5.2 (*Right to Defend in the Sanofi Territory*) and Section 10.5.3 (*Right to Defend in the Fulcrum Territory*), the Party that is responsible for the applicable defense (the "**Defending Party**") will keep the other Party (the "**Co-Defending Party**") reasonably informed of the status and progress of such defense. The Defending Party will reasonably consult with the Co-Defending Party, including using

reasonable efforts to take the Co-Defending Party's reasonable and timely comments into good faith consideration with respect to such defense. The Co-Defending Party will also provide reasonable assistance in connection with such defense, including by executing reasonably appropriate documents, cooperating in discovery and joining as a party to the action if required. Each Party will bear its own costs and expenses under this Section 10.5 (*Third Party Infringement Claims*).

10.6 Patent Challenges of Third Party Patent Rights.

10.6.1 **Notice of Third Party Patent Right**. If either Party becomes aware of a Third Party Patent Right that might form the basis for a claim that the Exploitation of a Licensed Product anywhere in the world infringes, or will infringe, such Patent Right, then the Party first obtaining knowledge of such Patent Right will promptly notify the other Party, with and the Parties will promptly meet to discuss the matter.

10.6.2 **Patent Challenges of Third Party Patents**.

(a) Fulcrum will have the first right, but not the obligation, to prosecute a Patent Challenge of such Third Party Patent Right in the Fulcrum Territory using counsel of its choosing, *provided*, *however*, if Fulcrum chooses not to initiate such a Patent Challenge without a strategic reason, Sanofi will have the second right, but not the obligation, to do so. Following discussion and coordination by the Parties, Sanofi may prosecute a parallel Patent Challenge of such Third Party Patent Right in the Fulcrum Territory using counsel of its choosing.

(b) Sanofi will have the first right, but not the obligation, to initiate a Patent Challenge of such Third Party Patent Right in the Sanofi Territory using counsel of its choosing, *provided*, *however*, if Sanofi chooses not to initiate such a Patent Challenge without a strategic reason, Fulcrum will have the second right, but not the obligation, to do so. Following discussion and coordination by the Parties, Fulcrum may prosecute a parallel Patent Challenge of such Third Party Patent Right in the Sanofi Territory using counsel of its choosing.

(c) The Party initiating such Patent Challenge will (i) keep the other Party reasonably informed regarding any such Patent Challenge, including by providing the other Party with copies of all material and substantive pleadings and other documents filed in any proceeding relating to such Patent Challenge, (ii) consider timely and reasonable input from the other Party during the course of the Patent Challenge, and (iii) provide the other Party with the opportunity to attend any material substantive meetings, hearings, or other proceedings related to such Patent Challenge (together with its own counsel, at its own expense) and to review and comment on all substantive documents related to such Patent Challenge prior to filing or submission of such documents. The Parties will reasonably assist each other and cooperate and share information with respect to any such Patent Challenge. Each Party will bear its own costs and expenses with respect to any such Patent Challenge.

10.7 Restrictions on Settlement. Neither Party may (a) stipulate or otherwise agree that any Fulcrum Patent Right or Collaboration Patent Right is invalid or unenforceable; (b) stipulate or otherwise agree that any Licensed Compound or Licensed Product infringes or otherwise violates any Third Party intellectual property; or (c) incur any costs or liability of the other Party with respect to any

action taken with respect to Third Party intellectual property, in each case (a), (b) or (c), without the other Party's prior written consent, which consent may not be unreasonably withheld, conditioned or delayed.

10.8 Patent Term Extensions; Patent Listings.

10.8.1 **Patent Term Extensions**. With respect to any system for extending the term of Patent Rights in the Sanofi Territory during the Term that is similar to the patent term extension system in the U.S., Sanofi will be solely responsible for making all decisions regarding patent term extensions in the Sanofi Territory with respect to the Licensed Products, including supplementary protection certificates and any other extensions that are now or become available in the future, that are applicable to Fulcrum Patent Rights or Collaboration Patent Rights licensed hereunder and that become available directly as a result of the Regulatory Approval of a Licensed Product in the Sanofi Territory; *provided* that Sanofi will consult with Fulcrum with respect to such decisions and consider in good faith the timely and reasonable comments and concerns of Fulcrum. Fulcrum and Sanofi will cooperate in connection with all such activities. For clarity, Fulcrum will be solely responsible for making all decisions regarding patent term extensions with respect to Licensed Products in the Fulcrum Territory.

10.8.2 **Patent Listings**. As between the Parties, (a) Sanofi will have the sole and exclusive right to make all patent listings of Patent Rights or other Patent Right-related submissions with Regulatory Authorities for the Licensed Compounds and Licensed Products with respect to the Sanofi Technology (as well as any other intellectual property owned or Controlled by Sanofi); and (b) Fulcrum will have the sole and exclusive right to make all patent listings of Patent Rights or other Patent Right-related submissions with Regulatory Authorities for the Licensed Compounds and Licensed Products with respect to the Fulcrum Technology (as well as any other intellectual property owned or Controlled by Fulcrum). If applicable, the non-submitting Party will cooperate with the submitting Party's reasonable requests in connection therewith, including meeting any submission deadlines, to the extent required or permitted by Applicable Law.

10.9 Unified Patent Court.

10.9.1 **Definitions.** Capitalized terms in this Section 10.9 (*Unified Patent Court*) will have the meaning given to such terms in the Rules of Procedure of the Unified Patent Court as adopted by decision of the Administrative Committee on 8 July 2022 and established by the Agreement on a Unified Patent Court of 19 February 2013 (OJ C 175, 20.6.2013, p. 1) (including any subsequent amendments).

10.9.2 **General.** Sanofi will be solely responsible for making all decisions regarding the opting-out or opting-in of existing Patent Rights into the jurisdiction of the Unified Patent Court or the registration of Patent Rights with Unitary Effect.

10.9.3 **Opt-Out and Withdrawal of Opt-Out**. Notwithstanding any provision to the contrary hereunder, Sanofi will have the following rights:

(a) With respect to any Patent Rights that are co-owned by Sanofi and Fulcrum, Sanofi shall have the sole right (but not the obligation), at its sole expense and sole discretion, to (i) file an application to Opt-Out any European Patent from the exclusive competence of the Unified Patent Court or (ii) lodge an application to

Withdraw an Opt-Out with respect to any European Patent from the exclusive competence of the Unified Patent Court, in accordance with Applicable Laws (including Article 83 of Unified Patent Court Agreement and Rule 8 of the Rules of Procedure of the Unified Patent Court). Fulcrum will provide on request any evidence or signed document needed for a valid Opt-Out, or a valid Withdrawal of an Opt-Out;

(b) With respect to the Patent Rights owned by Fulcrum, Fulcrum will, at Sanofi's sole discretion, cost and expense, as soon as reasonably practicable after a request by Sanofi, and no later than [***] after the request, (i) file an application to Opt-Out any European Patent specified by Sanofi from the exclusive competence of the Unified Patent Court, pay any prescribed fee, and take any action as may be necessary or useful to secure the Opt-Out, or (ii) lodge an application to Withdraw an Opt-Out with respect to any European Patent specified by Sanofi from the exclusive competence of the Unified Patent Court, pay any prescribed fee, and take any action as may be necessary or useful to secure the Withdrawal, in accordance with Applicable Laws (including Article 83 of Unified Patent Court Agreement and Rule 5 of the Rules of Procedure of the Unified Patent Court). Sanofi shall provide on request any evidence or signed document needed for a valid Opt-Out, or a valid Withdrawal of an Opt-Out.

10.9.4 **Unitary Patents**, **Request for Unitary Effect.** Notwithstanding any provision to the contrary hereunder, Sanofi will have the following rights:

(a) With respect to any Patent Rights that are co-owned by Sanofi and Fulcrum, Sanofi will have the sole right (but not the obligation), at its sole expense, to file a request for Unitary Effect for any granted European Patent. Fulcrum shall provide on request any evidence or signed document needed for a valid request for Unitary Effect.

(b) With respect to the Patent Rights owned by Fulcrum, Fulcrum will, at Sanofi's sole cost and expense, as soon as reasonably practicable after a request by Sanofi, but in any case no later than [***] after the mention of the grant in the European Patent Bulletin, (i) file a request for Unitary Effect for any granted European Patent specified by Sanofi, and (ii) take such other actions as may be necessary or useful to secure the request for Unitary Effect of such European granted patent including filing any required translation referred to in Article 6.1. of Regulation (EU) No. 1260/2012.

10.9.5 **Cooperation.** Sanofi will consult with Fulcrum with respect to such decisions and will consider the timely and reasonable comments and concerns of Fulcrum in good faith.

10.10 Common Interest. All information exchanged between the Parties regarding the prosecution, maintenance, enforcement, and defense of Patent Rights or a Patent Challenge with respect to a Third Party's Patent Rights under this Article 10 (*Intellectual Property*) will be the Confidential Information of the disclosing Party. In addition, the Parties stipulate and agree that, with regard to such prosecution, maintenance, enforcement, and defense the interests of the Parties as collaborators and licensor and licensee are to obtain the strongest patent protection possible for the Licensed Compounds and Licensed Products, and as such, are aligned and are legal in nature. The Parties stipulate and agree that they have not waived, and nothing in this Agreement constitutes a waiver of, any legal privilege concerning the Patent Rights under this Article 10 (*Intellectual*

Property), including privilege under the common interest doctrine and similar or related doctrines. Notwithstanding any provision to the contrary set forth in this Agreement, to the extent a Party has a good faith belief that any information required to be disclosed by such Party to the other Party under this Article 10 (*Intellectual Property*) is protected by attorney-client privilege or any other applicable legal privilege or immunity, such Party will not be required to disclose such information and the Parties will in good faith cooperate to agree upon a procedure (including entering into a specific common interest agreement, disclosing such information on a "for counsel eyes only" basis or similar procedure) under which such information may be disclosed without waiving or breaching such privilege or immunity.

10.11 Product Trademarks.

10.11.1 **Ownership**.

(a) **Ownership of Sanofi Product Trademarks**. As between the Parties, Sanofi will have the sole right to determine and will own all right, title and interest in and to the Trademarks to be used by Sanofi or its Affiliates or its or their Sublicensees for the Commercialization of Licensed Product in the Sanofi Territory excluding any trademarks, service marks, names or logos that include any corporate name or logo of the Parties or their Affiliates or its or their Sublicensees ("**Sanofi Product Trademarks**"); *provided* that such Sanofi Product Trademarks are consistent and do not conflict with the Joint Commercialization Strategy. Fulcrum will not and will not permit its Affiliates or licensees to, (i) use in their respective businesses, any Trademark that is confusingly similar to, misleading or deceptive with respect to or that dilutes any (or any part) of the Sanofi Product Trademarks, and (ii) do any act that endangers, destroys, or similarly affects, in any material respect, the value of the goodwill pertaining to the Sanofi Product Trademarks. Fulcrum will not and will not permit its Affiliates or licensees to, attack, dispute or contest the validity of or ownership of any Sanofi Product Trademark anywhere in the Sanofi Territory or any registrations issued or issuing with respect thereto.

(b) **Ownership of Fulcrum Product Trademarks**. As between the Parties, Fulcrum will have the sole right to determine and will own all right, title and interest in and to the Trademarks to be used by Fulcrum or its Affiliates or its or their Sublicensees for the Commercialization of Licensed Product in the Fulcrum Territory excluding any trademarks, service marks, names or logos that include any corporate name or logo of the Parties or their Affiliates or its or their Sublicensees ("**Fulcrum Product Trademarks**"); *provided* that such Fulcrum Product Trademarks are consistent and do not conflict with the Joint Commercialization Strategy. Sanofi will not and will not permit its Affiliates or sublicensee to, (i) use in their respective businesses, any Trademark that is confusingly similar to, misleading or deceptive with respect to or that dilutes any (or any part) of the Fulcrum Product Trademarks, and (ii) do any act that endangers, destroys, or similarly affects, in any material respect, the value of the goodwill pertaining to the Fulcrum Product Trademarks. Sanofi will not and will not permit its Affiliates to, attack, dispute or contest the validity of or ownership of any Fulcrum Product Trademark anywhere in the Fulcrum Territory or any registrations issued or issuing with respect thereto.

(c) **Ownership of Jointly-Determined Brand Names**. In the event the Parties choose a brand name for the Commercialization of a Licensed Product in the Territory in accordance with Section 3.4.3(a) (*Specific Responsibilities of the JCC*) that is

covered by a Trademark for which Fulcrum commenced Trademark prosecution in the Sanofi Territory prior to such selection, then Fulcrum shall grant, and hereby grants, to Sanofi an exclusive (even as to Fulcrum), transferable (pursuant to Section 16.1 (*Assignment*)), sublicensable (through multiple tiers), fully paid-up license free of royalties or other payment obligations (except as otherwise set forth in Article 9 (*Payments*)) to such brand name for the Commercialization of such Licensed Product in the Sanofi Territory. Any and all such Trademarks shall be deemed Sanofi Product Trademarks for any and all purposes under this Agreement (including, without limitation, for purposes of Section 10.11.3 (*Prosecution of Product Trademarks*), Section 10.11.4 (*Enforcement of Product Trademarks*) and Section 10.11.5 (*Third Party Claims*)), other than Section 14.8.2 (*Sanofi Product Trademarks*); *provided* that Fulcrum shall own all right, title and interest in and to such Trademarks and each Party will comply with the quality control standards set forth in Section 10.11.1(a) (*Ownership of Sanofi Product Trademarks*).

10.11.2 **Notice**. Each Party will provide to the other Party prompt written notice of any actual or threatened infringement of the Sanofi Product Trademarks or Fulcrum Product Trademarks in the Territory and of any actual or threatened claim that the use of the Sanofi Product Trademarks or Fulcrum Product Trademarks in the Territory violates the rights of any Third Party, in each case, of which such Party becomes aware.

10.11.3 **Prosecution of Product Trademarks**.

(a) **Sanofi Product Trademarks**. Sanofi will have the sole right to register, prosecute and maintain the Sanofi Product Trademarks in using counsel of its own choice. All costs and expenses of registering, prosecuting and maintaining the Sanofi Product Trademarks in the Territory will be borne solely by Sanofi.

(b) **Fulcrum Product Trademarks**. Fulcrum will have the sole right to register, prosecute and maintain the Fulcrum Product Trademarks in using counsel of its own choice. All costs and expenses of registering, prosecuting and maintaining the Fulcrum Product Trademarks in the Territory will be borne solely by Fulcrum.

10.11.4 **Enforcement of Product Trademarks**.

(a) **Sanofi Product Trademarks**. Sanofi will have the sole right to take such action as Sanofi deems necessary against a Third Party based on any alleged, threatened or actual infringement, dilution, misappropriation or other violation of or unfair trade practices or any other like offense relating to, the Sanofi Product Trademarks by a Third Party in the Territory, at its sole cost and expense and using counsel of its own choice. Sanofi will retain any damages or other amounts collected in connection therewith.

(b) **Fulcrum Product Trademarks**. Fulcrum will have the sole right to take such action as Fulcrum deems necessary against a Third Party based on any alleged, threatened or actual infringement, dilution, misappropriation or other violation of or unfair trade practices or any other like offense relating to, the Fulcrum Product Trademarks by a Third Party in the Territory, at its sole cost and expense and using counsel of its own choice. Fulcrum will retain any damages or other amounts collected in connection therewith.

(c) **Cooperation**. The non-enforcing Party shall provide reasonable assistance to the enforcing Party, at such enforcing Party's expense, with respect to any enforcement activities with respect to a Sanofi Product Trademark or Fulcrum Product Trademark, as applicable, under this Section 10.11.4 (*Enforcement of Product Trademarks*), including providing access to relevant documents and other evidence, making its employees reasonably available during business hours, and joining the action to the extent necessary to maintain the action.

10.11.5 **Third Party Claims**.

(a) **Sanofi Product Trademarks**. Sanofi will have the sole right to defend against and settle any alleged, threatened or actual claim by a Third Party that the use or registration of the Sanofi Product Trademarks in the Territory infringes, dilutes, misappropriates or otherwise violates any Trademark or other right of that Third Party or constitutes unfair trade practices or any other like offense or any other claims as may be brought by a Third Party against a Party in connection with the use of the Sanofi Product Trademarks with respect to the Licensed Products in the Sanofi Territory, at its sole cost and expense and using counsel of its own choice. Sanofi will retain any damages or other amounts collected in connection therewith.

(b) **Fulcrum Product Trademarks**. Fulcrum will have the sole right to defend against and settle any alleged, threatened or actual claim by a Third Party that the use or registration of the Fulcrum Product Trademarks in the Territory infringes, dilutes, misappropriates or otherwise violates any Trademark or other right of that Third Party or constitutes unfair trade practices or any other like offense or any other claims as may be brought by a Third Party against a Party in connection with the use of the Fulcrum Product Trademarks with respect to the Licensed Products in the Fulcrum Territory, at its sole cost and expense and using counsel of its own choice. Fulcrum will retain any damages or other amounts collected in connection therewith.

10.11.6 **Cooperation**. Each Party will, and will cause its Affiliates to, assist and cooperate with the other Party, as may be reasonably requested by a Party from time to time, in connection with its activities set forth in this Section 10.11 (*Product Trademarks*), including where necessary, furnishing a power of attorney solely for such purpose or joining in, or being named as a necessary party to, such action, providing access to relevant documents and other evidence and making its employees available at reasonable business hours; *provided* that the requesting Party will reimburse the other Party for its reasonable and verifiable External Costs incurred in connection therewith.

10.12 Falsified Medicines. Without limiting either Party's rights or obligations under Section 10.3 (*Enforcement Against Third Party Infringement or Misappropriation*):

10.12.1 **Notification**. Each Party will promptly notify the other Party in writing if it becomes aware of any Third Party's manufacturing, sale, offer for sale, distribution or contribution to the manufacturing, shipment or commercialization of a medical product purporting to be a Licensed Product which deliberately or fraudulently misrepresents its identity, composition or source ("**Falsified Medicine**").

10.12.2 **Sanofi Territory**. Sanofi will have the sole and exclusive right, but not the obligation, to lead any detection program, investigation or collaboration with any Governmental

Authority and the sole and exclusive right, but not the obligation, to file or threaten to file a claim or lawsuit to enforce any rights against any Third Party manufacturing, selling, offering for sale or distributing Falsified Medicines or contributing to any of these actions in the Sanofi Territory. If requested by Sanofi, Fulcrum will reasonably cooperate with Sanofi with respect to any suspected Falsified Medicines to provide complementary information related to the applicable Licensed Product when necessary or requested by any Governmental Authority.

10.12.3 **Fulcrum Territory**. Fulcrum will have the sole and exclusive right, but not the obligation, to lead any detection program, investigation or collaboration with any Governmental Authority and the sole and exclusive right, but not the obligation, to file or threaten to file a claim or lawsuit to enforce any rights against any Third Party manufacturing, selling, offering for sale or distributing Falsified Medicines or contributing to any of these actions in the Fulcrum Territory. If requested by Fulcrum, Sanofi will reasonably cooperate with Fulcrum with respect to any suspected Falsified Medicines to provide complementary information related to the applicable Licensed Product when necessary or requested by any Governmental Authority.

ARTICLE 11
REPRESENTATIONS, WARRANTIES, AND COVENANTS

11.1 Mutual Representations and Warranties. Each of Sanofi and Fulcrum hereby represents and warrants to the other Party as of the Effective Date that:

11.1.1 It is a corporation or limited company duly organized, validly existing, and in good standing under the laws of the jurisdiction of its organization, and it has the full right, power, and authority to enter into this Agreement and to perform its obligations hereunder.

11.1.2 All consents, approvals, and authorizations from all Governmental Authorities or other Third Parties required to be obtained by such Party in connection with this Agreement have been obtained.

11.1.3 The execution, delivery, and performance of this Agreement by it has been duly authorized by all requisite corporate action.

11.1.4 The execution and delivery of this Agreement and the performance of its obligations hereunder (a) do not conflict with or violate any requirement of Applicable Law or any provision of its articles of incorporation, bylaws, limited partnership agreement, or any similar instrument, as applicable, in any material way, (b) do not conflict with, violate, or breach or constitute a default or require any consent under, any Applicable Law or any contractual obligation or court or administrative order by which it is bound and (c) do not conflict and are not inconsistent with any agreement of such Party or its Affiliates with or rights granted by such Party or its Affiliates to any other Person.

11.1.5 To its Knowledge, it has not, directly or indirectly, offered, promised, paid, authorized, or given to any Government Official or Other Covered Party for the purpose, pertaining to this Agreement, of: (a) influencing any act or decision of the Government Official or Other Covered Party; (b) inducing the Government Official or Other Covered Party to do or omit to do an act in violation of a lawful duty; (c) securing any improper advantage; or (d) inducing the Government Official or Other Covered Party to influence the act or decision

of a government or government instrumentality, in order to obtain or retain business, or direct business to, any Person, in each case in any way related to this Agreement.

11.1.6 It is not aware of any Government Official or Other Covered Party having any financial interest in the subject matter of this Agreement or in any way personally benefiting, directly, or indirectly, from this Agreement.

11.1.7 It is in compliance with all applicable global trade laws (including the Global Trade Control Laws), including those related to import controls, export controls, or economic sanctions. It is not, nor is any of its Affiliates or its or their respective directors, officers, employees, agents, or representatives, or in the last [***] was, a Restricted Party.

11.1.8 (a) Neither it nor any of its or its Affiliates' employees, agents or independent contractors performing under this Agreement, or in the case of Fulcrum, no employee, agent or independent contractor engaged by Fulcrum or its Affiliates in the Development of Licensed Compound or any Licensed Product prior to the Effective Date, has ever been or is currently: (i) debarred or suspended under 21 U.S.C. §335(a) or (b) or its equivalent in the Territory, (ii) the subject of a conviction described in Section 306 of the FD&C Act or its equivalent in the Territory, (iii) excluded, debarred, suspended or otherwise ineligible to participate in a federal or governmental health care program, debarred from federal contracting, convicted of or pled *nolo contendere* to any felony, or to any federal or state legal violation (including misdemeanors) relating to prescription drug products or fraud, (iv) subject to OFAC sanctions or on the OFAC list of specially designated nationals, or (v) subject to any similar sanction of any Governmental Authority in the Territory ("**Debarred/Excluded**"), (b) no proceeding that could result in it being Debarred/Excluded is pending, and (c) neither it nor any of its Affiliates has used, in any capacity in the performance of obligations relating to the Licensed Compounds and Licensed Products, any employee, subcontractor, consultant, agent, representative, or other Person who has been Debarred/Excluded.

11.2 Additional Fulcrum Representations and Warranties. Except as may be qualified by the disclosure letter dated as of the Effective Date provided by Fulcrum to Sanofi, Fulcrum hereby represents and warrants as of the Effective Date to Sanofi that:

11.2.1 It has the full right, power and authority to grant all of the rights and licenses granted to Sanofi under this Agreement, including under the Fulcrum Technology, and it has not granted any license or other right under the Fulcrum Technology that is inconsistent with the licenses granted to Sanofi hereunder.

11.2.2 Fulcrum owns or has a valid right to use the Fulcrum Technology existing as of the Effective Date (including through its control of its Affiliates), including the Fulcrum Patent Rights listed on **Schedule 1.83** (*Fulcrum Patent Rights*) and the Fulcrum Know-How listed on **Schedule 4.1** (*Initial Technology Transfer*). With respect to any Fulcrum Patent Right identified on **Schedule 1.83** (*Fulcrum Patent Rights*) as being solely owned by Fulcrum, Fulcrum owns all rights, title, and interests in and to such Fulcrum Patent Rights, free and clear of any liens, encumbrances, and security interests. **Schedule 1.83** (*Fulcrum Patent Rights*) sets forth a complete and accurate list of all Fulcrum Patent Rights existing as of the Effective Date. Neither Fulcrum nor any of its Affiliates owns or holds rights to any Patent Rights, Know-How, or biological or chemical materials that would be necessary for the Exploitation of the Licensed Compound or Licensed Product in the form it exists as

of the Effective Date but for the fact that Fulcrum or such Affiliate does not Control such Patent Right, Know-How or other materials.

11.2.3 Fulcrum has complied in all material respects with Applicable Law with respect to the prosecution and maintenance of the Fulcrum Patent Rights. Neither Fulcrum nor its Affiliates have received any written notice of any claim or threat of a claim or litigation made by any Person against Fulcrum or its Affiliates that alleges that any Fulcrum Patent Right is invalid or unenforceable and there is no pending, or to Fulcrum's Knowledge, threatened, adverse action, suit or proceeding against Fulcrum in relation to any Fulcrum Patent Right. All Fulcrum Patent Rights are: (a) subsisting and, to Fulcrum's Knowledge, not invalid or unenforceable, in whole or in part; (b) in the case of pending applications, to Fulcrum's Knowledge, being diligently prosecuted in the respective patent offices in accordance with Applicable Law and Fulcrum has presented all relevant references, documents and information of which it and the inventors are aware to the relevant patent examiner at the relevant patent office; and (c) being prosecuted and maintained in accordance with the policies and procedures of the applicable patent office, including that (i) every inventor of the claims thereof has been identified in accordance with the Applicable Laws of the relevant jurisdiction in which such Patent Right is issued or pending and (ii) all applicable fees required by such patent office have been paid by the due date for payment. To Fulcrum's Knowledge, there is no reference or prior art that would anticipate the issuance of any claim pending as of such date within any Fulcrum Patent Right.

11.2.4 To Fulcrum's Knowledge, it has not misappropriated, infringed or otherwise violated any intellectual property right of a Third Party in connection with Developing the Licensed Compound and Licensed Product in the form it exists as of the Effective Date. To Fulcrum's Knowledge, the use and practice of the Fulcrum Technology as contemplated by this Agreement as of the Effective Date does not and will not infringe, misappropriate or otherwise violate any intellectual property rights (including trade secrets) of any Third Party.

11.2.5 There is no pending or, to Fulcrum's Knowledge, potential or threatened litigation, nor has Fulcrum received any notice from any Third Party, asserting or alleging that the Exploitation of the Licensed Compounds or Licensed Products prior to the Effective Date infringed or misappropriated, or currently infringes or misappropriates, the intellectual property rights of such Third Party.

11.2.6 There are no pending or, to Fulcrum's Knowledge, potential or threatened, adverse actions, suits, or proceedings against Fulcrum involving the Fulcrum Technology, Licensed Compounds or Licensed Products, or which could reasonably be expected to adversely affect or restrict the ability of (a) Fulcrum to consummate or perform the transactions and obligations contemplated under this Agreement or (b) Sanofi to Exploit the Licensed Compounds or Licensed Products (including, in each case, any intermediate or component thereof) as contemplated by this Agreement.

11.2.7 To the Knowledge of Fulcrum, there are no activities by Third Parties that constitute infringement or misappropriation of, or otherwise violate, the Fulcrum Technology (in the case of pending claims, evaluating them as if issued).

11.2.8 There are no legal claims, judgments, or settlements against or owed by Fulcrum or any of its Affiliates, or pending or, to Fulcrum's Knowledge, threatened, legal claims or litigation, in each case, relating to antitrust, anti-competition, or anti-corruption law violations.

11.2.9 **Schedule 1.61** (*Existing Third Party IP Agreements*) sets forth all Existing Third Party IP Agreements in effect as of the Effective Date, true, correct and complete copies of which have been provided to Sanofi prior to the date hereof except that certain terms (including financial terms) which do not affect the rights or obligations of Sanofi, its Affiliates, or Sublicensees under this Agreement have been redacted.

11.2.10 Each Existing Third Party IP Agreement is valid, binding, enforceable, and in full force and effect. No notice of breach, default, or termination has been received or given under any Existing Third Party IP Agreement, and, to Fulcrum's Knowledge, there is no act or omission by Fulcrum or any of its Affiliates that would provide a right to terminate any such agreement. To Fulcrum's Knowledge, no circumstances or grounds exist that would reasonably be expected to give rise to a claim of material breach or a right of rescission, termination, revision, or amendment of any of the Existing Third Party IP Agreements, including the execution, delivery and performance of this Agreement. Neither Fulcrum nor any of its Affiliates has waived any of their respective rights under any Existing Third Party IP Agreement in any manner that conflicts with or limits the scope of any of the rights or licenses granted to Sanofi hereunder, and, to Fulcrum's Knowledge, no such rights have lapsed or otherwise expired or been terminated. Fulcrum has obtained all consents and provided all notices required to be provided under each Existing Third Party IP Agreement in connection with the execution and delivery of this Agreement and the performance by the Parties of their respective obligations hereunder, and the execution, delivery, and performance of this Agreement by the Parties does not and will not constitute a breach or default under any of the Existing Third Party IP Agreements.

11.2.11 Other than the Existing Third Party IP Agreements, as of the Effective Date, there are no agreements between Fulcrum and any Third Party pursuant to which Fulcrum or any of its Affiliates Control any Fulcrum Technology licensed to Sanofi under this Agreement. Except for the Patent Rights or Know-How in-licensed under the Existing Third Party IP Agreements, neither Fulcrum nor its Affiliates has knowledge of any Patent Rights or Know-How Controlled by a Third Party that is necessary for the Development, Manufacture, Commercialization or other Exploitation of the Licensed Compounds or the Licensed Products, in each case, as contemplated as of the Effective Date and in accordance with the terms of this Agreement.

11.2.12 Neither Fulcrum nor any counterparty to any Existing Third Party IP Agreement has in writing alleged or threatened that the other party has breached an Existing Third Party IP Agreement (which has not been cured) or, to Fulcrum's Knowledge, threatened in writing to terminate an Existing Third Party IP Agreement.

11.2.13 There are no exclusivity provisions or any other restrictions in any agreement between Fulcrum or its Affiliates and any Third Party that would limit either Party's ability to Research, Develop, Manufacture, Commercialize or otherwise Exploit the Licensed Compounds or Licensed Products in the Field in the Territory. Neither Fulcrum nor any of its Affiliates are delinquent in any payment obligations to any Third Party, or engaged in any dispute with any Third Party, that would limit either Party's ability to Research, Develop, Manufacture, Commercialize or otherwise Exploit the Licensed Compounds or Licensed Products in the Field in the Territory.

11.2.14 Fulcrum and its Affiliates have obtained from all individuals who invented an Invention claimed in a Fulcrum Patent Right valid and enforceable written assignments of all rights of such individuals in such Fulcrum Technology. All such individuals presently assigned, and were under an enforceable legal obligation to assign, the Fulcrum Technology to Fulcrum at the time of the conception, discovery, development, creation or other making. To Fulcrum's Knowledge, no Person who claims to be an inventor of an Invention claimed in a Fulcrum Patent Right is not identified as an inventor of such invention in the filed patent documents for such Fulcrum Patent Right. No dispute regarding inventorship, authorship or ownership has been alleged or threatened with respect to any Fulcrum Technology.

11.2.15 Fulcrum and its Affiliates have taken commercially reasonable measures consistent with industry practices to protect the secrecy, confidentiality and value of all Fulcrum Know-How that constitutes trade secrets under Applicable Law, including by requiring all employees, consultants and subcontractors to execute agreements requiring all such employees, consultants and subcontractors to maintain the confidentiality of all such Fulcrum Know-How for customary time periods. To Fulcrum's Knowledge: (a) the Fulcrum Know-How has not been disclosed to, or used or discovered by, any Third Party except pursuant to such confidentiality agreements; and (b) there has not been a breach by any party of such confidentiality agreement.

11.2.16 Fulcrum and its Affiliates have prepared, maintained and retained all Regulatory Submissions for Licensed Compounds and Licensed Products pursuant to and in accordance with all Applicable Laws. Each Regulatory Submission filed by Fulcrum or its Affiliates with respect to a Licensed Compound or a Licensed Product prior to the Effective Date was true, complete and accurate and timely filed.

11.2.17 Fulcrum and its Affiliates have conducted and, to Fulcrum's Knowledge, their respective contractors and consultants have conducted, all Research, Development, Manufacture and other Exploitation of the Licensed Compounds and Licensed Products in accordance with all Applicable Law.

11.2.18 The Inventions claimed, covered or encompassed by the Fulcrum Technology: (a) were not conceived, discovered, developed, invented or otherwise made in connection with any research activities funded, in whole or in part, by the federal government of the United States (or any agency thereof) or the government of any other country; (b) are not a "subject invention" as that term is described in 35 U.S.C. §201(c); (c) are not otherwise subject to the provisions of the Patent and Trademark Law Amendments Act of 1980, codified at 35 U.S.C. §§200-212, or any regulations promulgated pursuant thereto, including in 37 C.F.R. Part 401; (d) in the case of clauses (b) or (c), are not subject to similar obligations or restrictions under the Applicable Law of any other country; and (e) are not the subject of any licenses, options or other rights of any Governmental Authority, within or outside the United States.

11.2.19 To Fulcrum's Knowledge, [***].

11.3 Additional Covenants. Each of Sanofi and Fulcrum hereby covenant to the other:

11.3.1 **Assignment of Inventions**. Each Party will require all of its and its Affiliates' employees and consultants and contractors to assign all Inventions that are conceived, discovered,

developed, invented or otherwise made by such employees according to the ownership principles described in Section 10.1 (*Inventions*).

11.3.2 **Compliance with Law**. It will, and will ensure that its Affiliates, comply with all Applicable Laws and, to the extent applicable, Professional Requirements, with respect to the performance of its obligations under this Agreement, including, as applicable, the Approved Labeling, the European Data Protection Directive 95/46/EC, the European General Data Protection Regulation (Regulation (EU) 2016/679), and any other applicable national data protection legislation.

11.3.3 **No Conflicts**. It will not enter into any agreement, contract, commitment or other arrangement, or otherwise take any action or fail to take any action, that could reasonably be expected to conflict with the rights granted to the other Party hereunder or otherwise prevent the other Party from exercising the rights granted to it hereunder.

11.3.4 **No Bribery**. It will not in the future offer, promise, pay, authorize, or give, money or anything of value, directly or indirectly, to any Government Official or Other Covered Party for the purpose, pertaining to this Agreement, of: (a) influencing any act or decision of the Government Official or Other Covered Party; (b) inducing the Government Official or Other Covered Party to do or omit to do an act in violation of a lawful duty; (c) securing any improper advantage; or (d) inducing the Government Official or Other Covered Party to influence the act or decision of a government or government instrumentality, in order to obtain or retain business, or direct business to, any Person, in each case, in any way related to this Agreement.

11.3.5 **Restricted Countries**. Neither it nor its Affiliates will export, transfer, or sell any Licensed Product (a) to any country or territory that is subject to comprehensive economic sanctions administered by OFAC, unless the sale of such Licensed Product would be permissible if Sanofi or its Affiliates or Sublicensees were subject to OFAC's jurisdiction, (b) to any other country or territory in which such activity would violate Applicable Law in the U.S., (c) to any Restricted Party unless the sale of such Licensed Product would be permissible if Sanofi or its Affiliates or Sublicensees was subject to OFAC's jurisdiction, or (d) in such a manner that would violate the Global Trade Control Laws.

11.3.6 **FCPA Compliance**. In performing under this Agreement, it and its Affiliates agree to comply with all applicable anti-corruption laws, including the Foreign Corrupt Practices Act of 1977 and the Bribery Act 2010, as amended from time-to-time; the anti-corruption laws of the Territory; and all laws enacted to implement the Organization for Economic Co-operation and Development Convention on Combating Bribery of Foreign Officials in International Business Transactions.

11.3.7 **Debarred/Excluded Persons**. It will not engage, in any capacity in connection with this Agreement or any ancillary agreements, any officer, employee, contractor, consultant, agent, representative, or other Person who has been Debarred/Excluded. Each Party will inform the other Party in writing promptly if it or any Person engaged by it or any of its Affiliates who is performing any obligations under this Agreement or any ancillary agreements is Debarred/Excluded, or if any action, suit, claim, investigation, or legal or administrative proceeding is pending or, to each Party's Knowledge, is threatened, pursuant to which a Party, any of its Affiliates or any such Person performing obligations hereunder or thereunder may become Debarred/Excluded.

11.3.8 **No Transfer of Title**.

(a) Except as expressly permitted under Section 16.1 (*Assignment*), Fulcrum covenants and agrees that during the Term, neither it nor its Affiliates shall enter into any agreement with any Third Party, whether written or oral, with respect to, or otherwise assign, transfer, license, or convey its right, title or interest in or to, the Fulcrum Technology, in each case, in a manner that is in conflict with the rights granted by Fulcrum to Sanofi under this Agreement or that would prevent Fulcrum from performing its obligations under this Agreement.

(b) Except as expressly permitted under Section 16.1 (*Assignment*), Sanofi covenants and agrees that during the Term, neither it nor its Affiliates shall enter into any agreement with any Third Party, whether written or oral, with respect to, or otherwise assign, transfer, license, or convey its right, title or interest in or to, the Fulcrum Technology or Sanofi Technology, in each case in a manner that is in conflict with the rights granted by Sanofi to Fulcrum under this Agreement or that would prevent Sanofi from performing its obligations under this Agreement.

11.4 Additional Fulcrum Covenants.

11.4.1 **Existing Third Party IP Agreements**. Fulcrum has provided a true, correct and complete copy of the Existing Third Party IP Agreements, and all amendments thereto, as of the Effective Date, in each case, subject to redactions of contents unrelated to this Agreement. Fulcrum will provide a true, correct and complete copy of all amendments, restatements, side letters, and other modifications to the Existing Third Party IP Agreements entered into after the Effective Date, in each case, subject to redactions of contents unrelated to this Agreement. Fulcrum will inform Sanofi of any action it may take under the Existing Third Party IP Agreements to the extent such action may impact Sanofi's interest under the Existing Third Party IP Agreements and consult with Sanofi with respect thereto. Without limiting the foregoing, Fulcrum shall: (a) fulfill in all material respects all of its obligations, including its payment obligations, under, and shall not otherwise breach in any material respect, the Existing Third Party IP Agreements and shall maintain the same in full force and effect (and to the extent permitted under such Existing Third Party IP Agreements, Sanofi shall have the right, in its sole discretion, to step in and cure any undisputed payment breach of such Existing Third Party IP Agreement by Fulcrum); (b) not assign (except an assignment to a party to which this Agreement has been assigned as permitted under Section 16.1 (*Assignment*)), amend, restate, amend and restate, terminate in whole or in part, or otherwise modify an Existing Third Party IP Agreement, or otherwise waive any rights under an Existing Third Party IP Agreement, in each case, in a manner in conflicts with the rights granted to Sanofi hereunder without the prior written consent of Sanofi, not to be unreasonably withheld, conditioned or delayed; (c) provide Sanofi with prompt notice of any claim of a breach under an Existing Third Party IP Agreement or notice of termination of any Existing Third Party IP Agreement; and (d) promptly send to Sanofi copies of all other material correspondence to or from the counterparty to an Existing Third Party IP Agreement to the extent related to this Agreement.

11.5 Disclaimer. EXCEPT AS EXPRESSLY SET FORTH HEREIN, EACH OF THE PARTIES EXPRESSLY DISCLAIMS ANY AND ALL REPRESENTATIONS AND WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, VALIDITY, OR ENFORCEABILITY OF THEIR RESPECTIVE INTELLECTUAL PROPERTY RIGHTS, AND

NONINFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, ARISING FROM A COURSE OF DEALING, USAGE, OR TRADE PRACTICES, IN ALL CASES WITH RESPECT THERETO. WITHOUT LIMITING THE FOREGOING, THE PARTIES AGREE THAT THE MILESTONE EVENTS AND NET SALES LEVELS SET FORTH IN THIS AGREEMENT OR THAT HAVE OTHERWISE BEEN DISCUSSED BY THE PARTIES ARE MERELY INTENDED TO DEFINE THE MILESTONE PAYMENTS AND ROYALTY OBLIGATIONS IF SUCH MILESTONE EVENTS OR NET SALES LEVELS ARE ACHIEVED. NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY, EITHER EXPRESS OR IMPLIED, THAT IT WILL BE ABLE TO SUCCESSFULLY ADVANCE ANY LICENSED PRODUCT OR RESEARCH, DEVELOP, ACHIEVE REGULATORY APPROVAL FOR, MANUFACTURE, COMMERCIALIZE OR OTHERWISE EXPLOIT ANY LICENSED PRODUCT OR, IF COMMERCIALIZED, THAT ANY PARTICULAR SALES LEVEL OR PROFIT OF SUCH LICENSED PRODUCT WILL BE ACHIEVED.

11.6 Limitation of Liability. NEITHER OF THE PARTIES, NOR ANY OF THEIR RESPECTIVE AFFILIATES, WILL BE ENTITLED TO RECOVER FROM THE OTHER PARTY OR ITS AFFILIATES, ANY SPECIAL, INCIDENTAL, INDIRECT, EXEMPLARY, CONSEQUENTIAL, OR PUNITIVE DAMAGES OR DAMAGES FOR LOSS OF PROFIT, LOSS OF REVENUE, OR LOST OPPORTUNITY IN CONNECTION WITH THIS AGREEMENT, ITS PERFORMANCE OR LACK OF PERFORMANCE HEREUNDER, OR ANY LICENSE GRANTED HEREUNDER, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES, EXCEPT TO THE EXTENT THE DAMAGES RESULT FROM A PARTY'S FRAUD, GROSS NEGLIGENCE OR INTENTIONAL MISCONDUCT, A BREACH OF THE OBLIGATIONS OF A PARTY UNDER ARTICLE 12 (*CONFIDENTIALITY*), OR AMOUNTS REQUIRED TO BE PAID TO A THIRD PARTY AS PART OF A CLAIM FOR WHICH A PARTY PROVIDES INDEMNIFICATION UNDER ARTICLE 13 (*INDEMNIFICATION*).

ARTICLE 12
CONFIDENTIALITY

12.1 Duty of Confidence. Subject to the other provisions of this Article 12 (*Confidentiality*):

12.1.1 except to the extent expressly authorized by this Agreement, all Confidential Information of a Party (the "**Disclosing Party**") will be maintained in confidence and otherwise safeguarded, and not published or otherwise disclosed to any Third Party without the Disclosing Party's prior written consent, by the other Party (the "**Receiving Party**") and its Affiliates;

12.1.2 the Receiving Party will treat all Confidential Information provided by the Disclosing Party, at a minimum, with the same degree of care as the Receiving Party uses for its own proprietary information of a similar nature, but in no event less than a reasonable degree of care;

12.1.3 the Receiving Party may only use any Confidential Information of the Disclosing Party for the purposes of performing its obligations or exercising its rights under this Agreement;

12.1.4 a Receiving Party may disclose Confidential Information of the Disclosing Party to: (a) such Receiving Party's Affiliates, and potential and actual licensees and Sublicensees; and (b) employees, directors, officers, agents, contractors, consultants, attorneys, accountants,

potential or actual investors solely for the purpose of evaluating or carrying out an actual or potential investment, acquisition or collaboration, and advisors of the Receiving Party and its Affiliates, licensees, and Sublicensees, in each case ((a) and (b)), to the extent reasonably necessary for the purposes of performing its obligations or exercising its rights under this Agreement; *provided* that (x) such Persons are bound by legally enforceable obligations of confidentiality and non-use with respect to the Disclosing Party's Confidential Information, or subject to professional ethical obligations of confidentiality, no less stringent than the confidentiality and non-use obligations set forth in this Agreement, except that the term of such obligation will be customary for such recipient of Confidential Information and (y) each Party remains responsible for any failure by its Affiliates, licensees, and Sublicensees, and its and its Affiliates', licensees', and Sublicensees' respective employees, directors, officers, agents, contractors, consultants, attorneys, accountants, investors and advisors, in each case, to treat such Confidential Information as required under this Section 12.1 (*Duty of Confidence*) (as if such Persons were Parties directly bound to the requirements of this Section 12.1 (*Duty of Confidence*)); and

12.1.5 each Party will promptly notify the other Party of any misuse or unauthorized disclosure of the other Party's Confidential Information.

The confidentiality, non-use, and non-disclosure obligations set forth in this Section 12.1 (*Duty of Confidence*) will be in full force and effect from the Effective Date until [***] after expiration or termination of this Agreement, *provided* that, with respect to any Know-How that is a trade secret and is identified as such by the Disclosing Party at the time of disclosure, the obligations of this Section 12.1 (*Duty of Confidence*) will continue for so long as such Know-How remains a trade secret.

12.2 Confidential Information. Any Development report provided by Fulcrum to Sanofi pursuant to Section 5.8 (*Development Reports*), any ROFN Notice and any notice provided by Fulcrum to Sanofi pursuant to Section 2.9 (*Change of Control of Fulcrum*) will be the Confidential Information of Fulcrum, with Sanofi deemed to be the Receiving Party of such information. The Fulcrum Know-How and any Know-How included in the Licensed Sanofi Technology, in each case, that is specifically related to the Licensed Products, Joint Collaboration Know-How and the terms of this Agreement will be the Confidential Information of both Parties, with each Party deemed to be the Receiving Party of such information. The Sanofi Know-How, any Development report provided by Sanofi to Fulcrum pursuant to Section 5.8 (*Development Reports*) and any Royalty Report will be the Confidential Information of Sanofi, with Fulcrum deemed to be the Receiving Party of such information. Except as provided in Section 12.4 (*Authorized Disclosures*) and Section 12.7 (*Publicity; Use of Names*), neither Party nor its Affiliates may disclose the existence or the terms of this Agreement without obtaining the prior written consent of the other Party.

12.3 Exemptions. Section 12.1 (*Duty of Confidence*) will not apply with respect to any portion of the Confidential Information of the Disclosing Party to the extent that the Receiving Party can demonstrate through competent evidence that such information:

12.3.1 was already known by the Receiving Party or any of its Affiliates without an obligation of confidentiality at the time of its receipt from the Disclosing Party, and not through a prior disclosure by or on behalf of the Disclosing Party, as documented by the Receiving Party's business records;

12.3.2 was generally available to the public or otherwise part of the public domain before its receipt from the Disclosing Party;

12.3.3 became generally available to the public or otherwise part of the public domain after its disclosure by the Disclosing Party other than through any act or omission of the Receiving Party or any of its Affiliates in breach of this Agreement;

12.3.4 is subsequently disclosed to the Receiving Party or any of its Affiliates without obligation of confidentiality by a Third Party who may rightfully do so and is not under a conflicting obligation of confidentiality to the Disclosing Party; or

12.3.5 is developed by the Receiving Party or any of its Affiliates independently and without use of or reference to any Confidential Information received from the Disclosing Party, as documented by the Receiving Party's business records.

No combination of features or disclosures will be deemed to fall within the foregoing exclusions merely because individual features are published or available to the general public or in the rightful possession of the Receiving Party or any of its Affiliates unless the combination itself and principle of operation are published or available to the general public or in the rightful possession of the Receiving Party or any of its Affiliates.

12.4 Authorized Disclosures.

12.4.1 **Permitted Circumstances**. Notwithstanding the obligations set forth in Section 12.1 (*Duty of Confidence*) and Section 12.7 (*Publicity; Use of Names*), a Party may disclose the other Party's Confidential Information (including this Agreement and the terms herein) in the following situations:

(a) solely to the extent reasonably necessary for the Receiving Party's prosecution or enforcement of Fulcrum Patent Rights, Collaboration Patent Rights, or Sanofi Patent Rights, in each case, as contemplated by this Agreement; *provided* that the Receiving Party will provide the Disclosing Party with at least [***] prior written notice of any such disclosure and take reasonable and lawful actions to avoid or minimize the degree of disclosure;

(b) to the extent related to this Agreement and necessary to submit Regulatory Submissions and other filings with Governmental Authorities (including Regulatory Authorities), as necessary for the Exploitation of the Licensed Products in accordance with the rights and obligations of the applicable Party under this Agreement;

(c) disclosure of this Agreement, its terms, and the status and results of Exploitation of the Licensed Compounds and Licensed Products to actual or *bona fide* potential investors, acquirors, (sub)licensees (including any counterparty to a Collaboration In-License), lenders, and other financial or commercial partners (including in connection with any royalty financing transaction), and their respective attorneys, accountants, banks, investors, and advisors, solely for the purpose of evaluating or carrying out an actual or potential investment, acquisition, (sub)license, debt transaction, or collaboration; *provided* that, in each such case, (i) with respect to actual or potential investors or financial partners (including in connection with any royalty financing transaction), the Receiving Party discloses the Agreement or its

terms on an outside counsel-basis only or otherwise with the prior written consent of the Disclosing Party, (ii) such Persons are bound by obligations of confidentiality and non-use, or subject to professional ethical obligations of confidentiality, at least as stringent as those set forth Article 12 (*Confidentiality*), except that the term of such obligation will be customary for such recipient of Confidential Information, (iii) for clarity, the disclosure is subject to the other Party's ability to review and redact business sensitive information under Section 12.4.2 (*Confidential Treatment*), (iv) the scope of any such disclosure is limited to the maximum extent practicable for the particular context in which it is being disclosed and (v) the Receiving Party remains responsible for any failure by any Person who receives Confidential Information from such Receiving Party pursuant to this Section 12.4.1(c) (*Permitted Circumstances*) to treat such Confidential Information as required under this Article 12 (*Confidentiality*);

(d) such disclosure is, in the reasonable opinion of the Receiving Party's legal counsel, required to comply with Applicable Law (whether generally or in pursuit of an application for listing of securities) including the United States Securities and Exchange Commission or equivalent foreign agency or regulatory body, or otherwise required by judicial or administrative process, *provided* that in each such event, as promptly as reasonably practicable and to the extent not prohibited by Applicable Law or judicial or administrative process, such Party will notify the other Party of such required disclosure and provide a draft of the disclosure to the other Party reasonably in advance of such filing or disclosure for the other Party's review and comment. The non-disclosing Party will provide any comments as soon as practicable, and the disclosing Party will reasonably consider in good faith any timely comments provided by the non-disclosing Party. Confidential Information that is disclosed in order to comply with Applicable Law or by judicial or administrative process pursuant to this Section 12.4.1(d) (*Permitted Circumstances*), in each case, will remain otherwise subject to the confidentiality and non-use provisions of this Article 12 (*Confidentiality*) with respect to the Party disclosing such Confidential Information, and such Party will take all steps reasonably necessary, including seeking of confidential treatment or a protective order for a period of at least [***] (to the extent permitted by Applicable Law or Governmental Authority), to ensure the continued confidential treatment of such Confidential Information, and each Party will be responsible for its own legal and other external costs in connection with any such filing or disclosure pursuant to this Section 12.4.1(d) (*Permitted Circumstances*);

(e) during the term of the GSK License Agreement, disclosure to GSK of (1) a copy of this Agreement and any amendments thereto, (2) those portions of Development reports and Royalty Reports related to Licensed Products and Licensed Compounds that are Covered by a Valid Claim of a GSK Patent Right that is included in the licenses granted to Sanofi under Section 2.1 (*License Grant to Sanofi*) and (3) results of any audits conducted with respect to Sanofi pursuant to Section 9.7.2 (*Audit Rights*); *provided*, in each case, that: (i) such information is provided to GSK as the Confidential Information of Fulcrum under the GSK License Agreement; (ii) Fulcrum redacts such documents to the maximum extent practicable to only the information required for GSK to determine Fulcrum's compliance with the terms of the GSK License Agreement; (iii) at least [***] in advance of such anticipated disclosure, Fulcrum shall permit Sanofi to review and

comment upon such proposed redactions described in the foregoing clause (ii) and shall implement any additional redactions that Sanofi reasonably requests and which do not redact information that Fulcrum is required to provide to GSK for GSK to determine Fulcrum's compliance with the terms of the GSK License Agreement; and (iv) Fulcrum will remain responsible for any failure by GSK to treat such Confidential Information as required under this Article 12 (*Confidentiality*); or

(f) disclosure pursuant to Section 12.6 (*Publication and Listing of Clinical Trials*) and Section 12.7 (*Publicity; Use of Name*).

12.4.2 **Confidential Treatment**. Notwithstanding any provision to the contrary set forth in this Agreement, in each case of a disclosure to be made pursuant to Section 12.4.1(c) (*Permitted Circumstances*) or Section 12.4.1(d) (*Permitted Circumstances*), where some or all of the terms of this Agreement are to be disclosed, the disclosing Party will provide to the other Party a redacted version of this Agreement to be made in connection with any such disclosure for review and comment by such other Party. In such event, the Parties will agree on a redacted version of this Agreement to be made in connection with any such disclosure, and the disclosing Party will not disclose or provide any redacted version of this Agreement that has not been agreed in writing by the other Party except in the case of a disclosure to *bona fide* potential acquirors or (sub)licensees (including any counterparty to a Collaboration In-License), in which case, the disclosing Party will be permitted to provide an unredacted copy of this Agreement to such Third Party in accordance with Section 12.4.1(c) excluding clause (iii) once the material terms of the deal with such Third Party are proposed to the board of directors of the disclosing Party. The immediately preceding sentence will not restrict either Party from making any disclosure to the extent required under any Applicable Law. Subject to the foregoing, but notwithstanding any other provision to the contrary set forth in this Agreement, if a Party is required or permitted to make a disclosure of the other Party's Confidential Information pursuant to Section 12.4.1 (*Permitted Circumstances*), then it will, to the extent not prohibited by Applicable Law or judicial or administrative process, except where impracticable, give reasonable advance notice to the other Party of such proposed disclosure and use reasonable efforts to secure confidential treatment of such information and will only disclose that portion of Confidential Information that is legally required to be disclosed as advised by its legal counsel. In any event, each Party agrees to take all reasonable action to avoid disclosure of Confidential Information of the other Party hereunder.

12.5 Joint Publication Strategy. Both Parties acknowledge that it is their policy for the studies and results thereof to be registered and published in accordance with their internal guidelines, and the Parties will cooperate and develop a joint publication strategy with respect to Clinical Trials conducted under the Global Development Plan in accordance with Section 3.4.3(b) (*Specific Responsibilities of the JCC*) and Section 3.1.5(d) (*Specific Responsibilities of the JSC*).

12.5.1 **Right to Publish**.

(a) **Publications under the Global Development Plan**. Neither Party will publicly present or publish any Clinical Trial protocol, Clinical Trial data, non-clinical data or preclinical data arising from any Clinical Trial conducted under the Global Development Plan (each such proposed presentation or publication, a "**Publication**"), *except* (i) with respect to the Global Phase 3 REACH Study, in which case Fulcrum may freely publish the data and results arising from such

Clinical Trial, and (ii) with respect to all other Clinical Trials, in accordance with the joint publication strategy as approved by the JCC in accordance with Section 3.4.3(b) (*Specific Responsibilities of the JCC*), and, in each case (i) and (ii), subject to the review process and additional limitations set forth in Section 12.5.1(c) (*Review Process and Other Limitations*), Section 12.5.1(d) (*Repeat Disclosures*) and Section 12.6 (*Publication and Listing of Clinical Trials*).

(b) **Publications under Sanofi Independent Development Plan and Fulcrum Independent Development Plan**. Each Party will have the sole right to publicly present or publish any (i) Clinical Trial data, non-clinical or preclinical data arising from any Clinical Trial and (ii) data arising from any non-clinical study conducted independently of any Clinical Trial, in each case ((i) and (ii)), conducted under the Sanofi Independent Development Plan or Fulcrum Independent Development Plan, as applicable, or otherwise conducted by such Party, subject to the review process and additional limitations set forth in Section 12.5.1(c) (*Review Process and Other Limitations*), Section 12.5.1(d) (*Repeat Disclosures*) and Section 12.6 (*Publication and Listing of Clinical Trials*).

(c) **Review Process and Other Limitations**. If a Party (the "**Publishing Party**") desires to publicly present or publish a Publication in accordance with Section 12.5.1(a) (*Publications under the Global Development Plan*) or Section 12.5.1(b) (*Publications under Sanofi Independent Development Plan and Fulcrum Independent Development Plan*), then such Party will provide the other Party (including the other Party's Alliance Manager and all members of the JCC) with a copy of such proposed Publication at least [***] prior to the earlier of its presentation or intended submission for publication (such applicable period, the "**Review Period**"). The Publishing Party will not submit or present any such Publication until (i) the other Party has provided written comments during such Review Period on the material in such Publication, or (ii) the applicable Review Period has elapsed without written comments from the other Party, in which case the Publishing Party may proceed and the Publication will be considered approved in its entirety. If the Publishing Party receives written comments from the other Party on any such Publication during the applicable Review Period, then it will consider the other Party's reasonable and timely comments in good faith and incorporate such comments where appropriate. Notwithstanding any provision to contrary set forth in this Agreement, the Publishing Party will (1) delete any Confidential Information of the other Party that such other Party identifies for deletion in such other Party's written comments, and (2) delay such Publication for a period of up to an additional [***] after the end of the applicable Review Period to enable the other Party to draft and file one or more patent applications with respect to any subject matter to be made public in such Publication. The Publishing Party will provide the other Party with a copy of the Publication at the time of the submission or presentation thereof. The Publishing Party agrees to determine the authorship of all Publications in accordance with all applicable International Committee of Medical Journal Editors (ICMJE) guidelines, and, in addition, to acknowledge the contributions of the other Party and the employees of the other Party, in each case, as scientifically appropriate.

(d) **Repeat Disclosures**. After a Publication has been made available to the public, each Party may post such Publication or a link to it on its corporate website or social media platforms (or any website managed by such Party in connection with

a Clinical Trial for the Licensed Products, as appropriate), *provided* that the information in such Publication remains true, correct, and the most current information with respect to the subject matters set forth therein, complies with Applicable Law and would not reasonably be expected to adversely impact the other Party; *provided*, *further*, that such Party will provide the other Party with a draft of such proposed Publication for the other Party's review and comment at least [***] prior to the proposed disclosure date.

12.6 Publication and Listing of Clinical Trials. With respect to the listing of Clinical Trials or the publication of Clinical Trial results for the Licensed Products and to the extent applicable to a Party's activities conducted under this Agreement, each Party will comply with (a) the Pharmaceutical Research and Manufacturers of America (PhRMA) Guidelines on the listing of Clinical Trials and the Publication of Clinical Trial results, and (b) any Applicable Law or applicable court order, stipulations, consent agreements, and settlements entered into by such Party. The Parties agree that any such listings or publications made pursuant to this Section 12.6 (*Publication and Listing of Clinical Trials*) will be considered a Publication for purposes of this Agreement and will be subject to Section 12.5 (*Joint Publication Strategy*).

12.7 Publicity; Use of Names.

12.7.1 **Press Release**.

(a) **Initial Press Release**. Fulcrum may issue an individual press release announcing this Agreement, as set forth on **Schedule 12.7.1** (*Press Release*), on such date and time as may be agreed by the Parties. Sanofi may choose in its sole discretion to provide a quote to be incorporated into such press release.

(b) **Press Releases and Public Announcements under Global Development Plan**. Neither Party will make a press release or other similar public disclosure with respect to any Clinical Trial data, non-clinical or preclinical data arising from any Clinical Trial conducted under the Global Development Plan without the other Party's prior written consent, except with respect to the Positive Data Readout in which case either Party may make a press release or other public disclosure, subject to the review process and additional limitations set forth in Section 12.7.1(d) (*Review Process and Other Limitations*) and Section 12.7.1(e) (*Repeat Disclosures*).

(c) **Press Releases and Public Announcements under Sanofi Independent Development Plan and Fulcrum Independent Development Plan**. Each Party will have the sole right to make a press release or other similar public disclosure with respect to any (i) Clinical Trial data, non-clinical or preclinical data arising from any Clinical Trial or (ii) data arising from any non-clinical study conducted independently of any Clinical Trial, in each case ((i) and (ii)), conducted by such Party under the Sanofi Independent Development Plan or Fulcrum Independent Development Plan, as applicable, subject to the review process and additional limitations set forth in Section 12.7.1(d) (*Review Process and Other Limitations*) and Section 12.7.1(e) (*Repeat Disclosures*).

(d) **Review Process and Other Limitations**. If either Party or any of its Affiliates desires to make a press release or other similar public disclosure in accordance with Section 12.7.1(b) (*Press Releases and Public Announcements under Global*

Development Plan) or Section 12.7.1(c) (*Press Releases and Public Announcements under Sanofi Independent Development Plan and Fulcrum Independent Development Plan*), such Party shall give at least [***] prior advance notice of the proposed content of such press release or announcement to the other Party for its prior review and approval, with such approval not to be unreasonably withheld, conditioned, or delayed (except as otherwise provided herein). A Party commenting on such a proposed press release or public disclosure shall provide its comments, if any, at least [***] prior to the proposed disclosure date. In relation to a Party's review of such a proposed press release or announcement, the Party may make specific, reasonable comments on such proposed press release or announcement within the prescribed time for commentary.

(e) **Repeat Disclosures**. The Parties agree that after (i) a disclosure pursuant to Section 12.7 (*Publicity; Use of Names*) or Section 12.4 (*Authorized Disclosures*) or (ii) the issuance of a press release (including the initial press release) or other public announcement pursuant to this Section 12.7.1 (*Press Release*) that has been reviewed and approved by the other Party, the disclosing Party may make subsequent public disclosures reiterating such information as previously reviewed and approved; *provided* that the information in such press release or other public announcement remains true, correct, and the most current information with respect to the subject matters set forth therein, complies with Applicable Law and would not reasonably be expected to adversely impact the other Party; *provided*, *further*, that such Party will provide the other Party with a draft of such proposed disclosure for the other Party's review and comment at least [***] prior to the proposed disclosure date.

12.7.2 **Use of Names**. Except as otherwise expressly set forth herein, neither Party (or any of its respective Affiliates) will use any corporate name, Trademark, service mark, trade name or logo of the other Party or any of its Affiliates, or its or their respective employees, in any publicity, promotion, news release or other public disclosure relating to this Agreement or its subject matter, without first obtaining the prior written consent of the other Party; *provided* that such consent will not be required (a) to the extent such use thereof may be required by Applicable Law, including the rules of any securities exchange or market on which a Party's or its Affiliate's securities are listed or traded, and (b) for either Party's use of the other Party's name and company logo, in accordance with written specifications and standards to be provided by the other Party to such Party, solely to identify the other Party as a collaborator on such Party's website and in public presentations. If a Party at any time determines that the use of such Party's name and company logo does not comply with standards provided by such Party and so notifies the other Party, then the other Party will cease using the first Party's name and company logo in such unapproved manner as soon as reasonably possible. Each Party (or its Affiliate, as applicable) will retain all rights, title and interests in and to all such corporate names, trademarks, trade names and logos of such Party and its Affiliates.

ARTICLE 13
INDEMNIFICATION

13.1 Indemnification by Fulcrum. Fulcrum will indemnify, hold harmless, and defend Sanofi and its Affiliates and their respective, directors, officers, employees, agents, successors, assigns and Sublicensees (the "**Sanofi Indemnitees**") from and against any and all Third Party suits, claims, proceedings, actions, and demands ("**Third Party Claims**") and all losses, liabilities, costs, claims,

damages, judgments, expenses, or losses (including reasonable attorneys' fees, court costs, witness fees, damages, judgments, fines, and amounts paid in settlement) arising therefrom ("**Losses**") to the extent that the applicable Third Party Claims and such Losses arise out of (a) a breach by Fulcrum of any of its representations, warranties, covenants, agreements or obligations under this Agreement, (b) the Exploitation of the Licensed Compounds and Licensed Products by or on behalf of Fulcrum or any of its Affiliates, licensees (not including Sanofi or its Affiliates, Sublicensees, or its subcontractors), Sublicensees, or subcontractors, (c) Fulcrum's failure to undertake any recall or product withdrawal of a Licensed Product in the Fulcrum Territory in accordance with Section 6.11 (*Recall, Withdrawal, or Field Alerts*), (d) the gross negligence, recklessness or willful misconduct of any Fulcrum Indemnitee or (e) any violation of Applicable Law by Fulcrum, its Affiliates, Sublicensees or subcontractors in connection with the performance of its obligations or exercise of its rights under this Agreement. Notwithstanding the foregoing, Fulcrum will not have any obligation to indemnify Sanofi Indemnitees to the extent that any Losses arise out of any Third Party Claim for which Sanofi is responsible for indemnifying Fulcrum pursuant to Section 13.2 (*Indemnification by Sanofi*).

13.2 Indemnification by Sanofi. Sanofi will indemnify, hold harmless, and defend Fulcrum and its Affiliates, and their respective directors, officers, employees, agents, successors, assigns and Sublicensees (the "**Fulcrum Indemnitees**") from and against any and all Losses, to the extent that the applicable Third Party Claims and such Losses arise out of (a) a breach by Sanofi of any of its representations, warranties, covenants, agreements or obligations under this Agreement, (b) the Exploitation of the Licensed Compounds and Licensed Products by or on behalf of Sanofi or any of its Affiliates, Sublicensees, or subcontractors, (c) Sanofi's failure to undertake any recall or product withdrawal of a Licensed Product in the Sanofi Territory in accordance with Section 6.11 (*Recall, Withdrawal, or Field Alerts*), (d) the gross negligence, recklessness or willful misconduct of any Sanofi Indemnitee or (e) any violation of Applicable Law by Sanofi, its Affiliates, Sublicensees or subcontractors in connection with the performance of its obligations or exercise of its rights under this Agreement. Notwithstanding any provision to the contrary set forth in this Agreement, Sanofi will not have any obligation to indemnify the Fulcrum Indemnitees to the extent that any Losses arise out of any Third Party Claim for which Fulcrum is responsible for indemnifying Sanofi pursuant to Section 13.1 (*Indemnification by Fulcrum*).

13.3 Indemnification Procedure. If either Party is seeking indemnification under Section 13.1 (*Indemnification by Fulcrum*) or Section 13.2 (*Indemnification by Sanofi*) (the "**Indemnified Party**"), then it will as soon as reasonably practicable inform the other Party (the "**Indemnifying Party**") of the Third Party Claim giving rise to such indemnification obligations (it being understood and agreed, however, that the failure or delay by an Indemnified Party to give such notice of a Third Party Claim will not affect the Indemnifying Party's indemnification obligations hereunder except to the extent the Indemnifying Party will have been actually and materially prejudiced as a result of such failure or delay to give notice). The Indemnifying Party will have the right to assume the defense of any such Third Party Claim for which it is obligated to indemnify the Indemnified Party by giving written notice to the Indemnified Party within [***] after receipt of notice of the Third Party Claim. The assumption of defense of the Third Party Claim shall not be construed as an acknowledgment that the Indemnifying Party is liable to indemnify any Indemnified Party in respect of the Third Party Claim, nor shall it constitute waiver by the Indemnifying Party of any defenses it may assert against the Indemnified Party's claim for indemnification. The Indemnified Party will cooperate with the Indemnifying Party and the Indemnifying Party's insurer as the Indemnifying Party may reasonably request, and at the Indemnifying Party's cost and expense. The Indemnified Party will have the right to participate, at its own expense and with counsel of its choice, in the defense of any Third Party that has been

assumed by the Indemnifying Party; *provided*, *however*, that the Indemnifying Party shall have the right to conduct the defense of the Third Party Claim with counsel of its choice. Neither Party will have the obligation to indemnify the other Party in connection with any settlement made without the Indemnifying Party's written consent, which consent will not be unreasonably withheld, conditioned, or delayed. The Indemnifying Party will not admit liability of the Indemnified Party or settle any Third Party Claim without the Indemnified Party's prior written consent, which consent will not be unreasonably withheld, conditioned, or delayed. If the Indemnifying Party does not assume and conduct the defense of the Third Party Claim as provided above, (a) the Indemnified Party may defend against, and consent to the entry of any judgment or enter into any settlement with respect to the Third Party Claim in any manner the Indemnified Party may deem reasonably appropriate (and the Indemnified Party need not consult with, or obtain any consent from, the Indemnifying Party in connection therewith), and (b) the Indemnified Party reserves any right it may have under this Article 13 (*Indemnification*) to obtain indemnification from the Indemnified Party. In the event that it is ultimately determined that the Indemnifying Party is not obligated to indemnify, defend or hold harmless the Indemnified Party from and against the Third Party Claim, the Indemnified Party will reimburse the Indemnifying Party for any and all costs and expenses (including attorneys' fees and expenses and costs of suit) and any Losses incurred by the Indemnifying Party in its defense of the Third Party Claim. If the Parties cannot agree as to the application of Section 13.1 (*Indemnification by Fulcrum*) or Section 13.2 (*Indemnification by Sanofi*) as to any Third Party Claim, then, pending resolution of the dispute pursuant to Article 15 (*Dispute Resolution; Governing Law*), the Parties may conduct separate defenses of such Third Party Claim, with each Party retaining the right to claim indemnification from the other Party in accordance with Section 13.1 (*Indemnification by Fulcrum*) or Section 13.2 (*Indemnification by Sanofi*), as applicable, upon resolution of the underlying Third Party Claim. In each case, the Indemnified Party will reasonably cooperate with the Indemnifying Party and will make available to the Indemnifying Party all pertinent information under the control of the Indemnified Party, which information will be subject to Article 12 (*Confidentiality*).

13.4 Insurance. During the Term and for a period of [***] thereafter, each Party will, at its own expense, procure and maintain insurance, including product liability insurance (with a Third Party insurance company with a current A.M. Best rating of A- or equivalent or higher, or solely with respect to Sanofi through a program of self-insurance), which insurance will be adequate to cover its obligations hereunder. Such insurance coverage will in no event be less than [***] per loss occurrence and [***] in the aggregate. It is understood that such insurance will not be construed to create a limit of either Party's liability with respect to its indemnification obligations under this Article 13 (*Indemnification*). Each Party will provide the other Party with written evidence of such insurance upon request. Each Party will provide the other Party with written notice at least [***] prior to the expiration, cancellation, nonrenewal, or material change in such insurance that materially adversely affects the rights of the other Party hereunder. To the extent insurance policies are written on claims-made form, such Party shall maintain the insurance coverage for a term of [***] after the termination or expiration of this Agreement or as legally required to maintain insurance, or when the last Clinical Trial subject receives treatment in connection with the Clinical Trial, including any treatment received after Clinical Trial completion.

ARTICLE 14
TERM AND TERMINATION

14.1 Term. The term of this Agreement will begin on the Effective Date and, unless earlier terminated in accordance with this Article 14 (*Term and Termination*), will continue, on a Licensed Product-by-Licensed Product and country-by-country basis until the expiration of the last Royalty Term for such Licensed Product (the "**Term**"). Upon expiration of this Agreement with respect to a Licensed

Product, the licenses granted in such country pursuant to Section 2.1 (*License Grant to Sanofi*) to Sanofi for such Licensed Product shall be exclusive, perpetual, irrevocable, fully paid-up and free of royalties or other payment obligations and, subject to the foregoing and except as set forth in Section 14.9 (*Survival; Accrued Rights*), all rights and obligations of the Parties under this Agreement with respect to such Licensed Products in such country shall cease.

14.2 Termination for Material Breach.

14.2.1 **Material Breach**. If either Party believes in good faith that the other is in material breach of this Agreement, then the non-breaching Party may deliver notice of such material breach to the other Party identifying the material breach in reasonable detail and a proposed remedy ("**Breach Notification**"). For any material breach arising from a failure to make a payment set forth in this Agreement, the allegedly breaching Party will have [***] from the receipt of the applicable Breach Notification to cure such material breach. For all material breaches other than a failure to make a payment as set forth in this Agreement, the allegedly breaching Party will have [***] from the date of the Breach Notification to cure such material breach. If the Party receiving notice of a material breach fails to cure that material breach within the applicable period set forth above, then the Party originally delivering the Breach Notification may terminate this Agreement in its entirety effective on written notice of termination to the other Party. In the event that a material breach is curable but the allegedly breaching Party demonstrates that it cannot be reasonably cured within the applicable cure period despite its diligent efforts, then the allegedly breaching Party will be allowed to continue to cure such material breach using diligent efforts for another [***] or a longer period if mutually agreed upon by the Parties.

14.2.2 **Disagreement as to Material Breach**. Notwithstanding Section 14.2.1 (*Material Breach*), if the Parties, reasonably and in good faith, disagree as to whether there has been a material breach of this Agreement, then: (a) the Party that disputes whether there has been a material breach may contest the allegation by referring such matter, within the cure period applicable to such alleged material breach, for resolution in accordance with Article 15 (*Dispute Resolution; Governing Law*); (b) the relevant cure period with respect to such alleged material breach will be tolled from the date on which the Party that disputes whether there has been a material breach notifies the other Party of such dispute and through the resolution of such dispute in accordance with Article 15 (*Dispute Resolution; Governing Law*); and (c) subject to Section 16.6 (*Force Majeure*), during the pendency of such dispute, all of the terms and conditions of this Agreement will remain in effect and the Parties will continue to perform all of their respective obligations hereunder.

14.3 Termination by Sanofi for Convenience. Sanofi will have the right to terminate the Agreement in its entirety or on a Licensed Product-by-Licensed Product or (a) country-by-country basis with respect to the Sanofi Major Countries or (b) Region-by-Region basis with respect to all other countries that are not Sanofi Major Countries (each such terminated jurisdiction, a "**Terminated Region**" and in the event of termination of this Agreement in its entirety, all countries in the Sanofi Territory will be Terminated Regions) at any time during the Term upon [***] prior written notice; *provided* that, if Sanofi terminates the Agreement under this Section 14.3 (*Termination by Sanofi for Convenience*) in all of the Sanofi Major Countries, European Region, the Asian Region, and the Latin American Region, then this Agreement will automatically terminate in its entirety.

14.4 Termination by Sanofi for Safety. Sanofi may terminate this Agreement for safety concerns with respect to a Licensed Product that are [***]: (a) in part on a Licensed Product-by-Licensed Product basis, where the safety concerns are with respect to a particular Licensed Product or (b) in its

entirety, where the safety concerns are with respect to all Licensed Products, in each case ((a) or (b)), upon [***] prior written notice to Fulcrum. Sanofi will include a summary of such safety concerns in such notice of termination.

14.5 Termination by Fulcrum for Sanofi's Cessation of Development and Commercialization.

14.5.1 **Shelving Event**. If, at any time during the period commencing on the earlier of the date of the Positive Data Readout for the Global Phase 3 REACH Study and Regulatory Approval for a Licensed Product in the Field in the Territory and ending on the tenth (10^{th}) anniversary of the First Commercial Sale of a Licensed Product in a Sanofi Major Country there is a consecutive [***] period during which (a) Sanofi and its Affiliates do not conduct any *bona fide* material Development or Commercialization activities with respect to any Licensed Compound or Licensed Product anywhere in the Territory for the benefit of the Sanofi Territory or (b) Sanofi has instituted and maintained (per Sanofi's internal policies) a hold on conducting all Development and Commercialization activities for Licensed Compounds or Licensed Products in the Territory, and such foregoing circumstances ((a) and (b)) are not:

(i) by written agreement of the Parties,

(ii) a result of any action or inaction by Fulcrum, its Affiliates or its or their respective directors, officers, employees, agents, successors or assigns for which Fulcrum has an obligation to indemnify Sanofi under Section 13.1 (*Indemnification by Fulcrum*),

(iii) a result of Sanofi's reasonable response to guidance from or action or inaction by a Regulatory Authority or Governmental Authority (such as a clinical hold, recall or withdrawal),

(iv) a result of Sanofi's internal regulatory decision-makers recommending, in accordance with Sanofi's internal policies, the cessation of Development or Commercialization activities with respect to a Licensed Compound or Licensed Product due to material concerns regarding the benefit:risk ratio of such Licensed Compound or Licensed Product,

(v) a failure beyond the reasonable control of Sanofi or its Affiliates to secure adequate supply of such Licensed Compound or Licensed Product, or

(vi) as a result, in whole or in part, of a Force Majeure Event or any claim brought by a Third Party against Sanofi, its Affiliate or Sublicensee that, through the grant of injunctive relief to a Third Party, prevents the continued conduct of Development or Commercialization activities with respect to a Licensed Compound or Licensed Product;

provided that, in the case of the foregoing clauses (iii), (iv) (v) and (vi), Sanofi keeps Fulcrum reasonably apprised of the circumstance and is working in good faith to overcome or remedy the underlying circumstance that serves as the basis of such exclusion (such circumstances described in the foregoing clauses ((a) and (b)), subject to the exclusions set forth in the foregoing clauses ((i)-(vi)), a "**Shelving Event**"), then Fulcrum will notify Sanofi in writing upon becoming aware of such Shelving Event having occurred. Within [***] following Sanofi's receipt of notice from Fulcrum regarding the existence of a

Shelving Event, the Parties shall meet (including via teleconference or videoconference) to discuss the nature and circumstances surrounding any such Shelving Event. Subject to Section 14.5.2 (*Disagreement as to Shelving Event*), Sanofi shall have [***] from such meeting date to cure such Shelving Event. If Sanofi fails to cure such Shelving Event within such [***] period or maintain such cure for at least [***], then Fulcrum may, at its election, terminate this Agreement in its entirety upon [***] prior written notice to Sanofi. For clarity, a Shelving Event can happen multiple times if this Agreement is not terminated due to a previous Shelving Event.

14.5.2 **Disagreement as to Shelving Event**. Notwithstanding Section 14.5.1 (*Shelving Event*), if the Parties in good faith disagree as to whether a Shelving Event has occurred: (a) Sanofi may contest such allegation by referring such matter, within [***] following the Parties' meeting to discuss the nature and circumstances surrounding such Shelving Event in accordance with Section 14.5.1 (*Shelving Event*), for resolution in accordance with Section 15.1 (*Dispute Resolution*); (b) the [***] cure period with respect to such alleged Shelving Event will be tolled from the date on which Sanofi notifies Fulcrum of such dispute through the resolution of such dispute in accordance with the applicable provisions of this Agreement; and (c) subject to Section 16.6 (*Force Majeure*), during the pendency of such dispute, all of the terms and conditions of this Agreement will remain in effect and the Parties will continue to perform all of their respective obligations hereunder.

14.6 Termination for Insolvency.

14.6.1 **Termination Right**. Each Party will have the right to terminate this Agreement in its entirety upon delivery of written notice to the other Party if (a) such other Party files in any court or agency pursuant to the United States Bankruptcy Code (the "**Code**") or any similar bankruptcy or insolvency law, foreign or domestic, (b) such other Party is served with a petition against it under the Code or any similar bankruptcy or insolvency law and such petition has not been discharged or dismissed within [***] of its filing, (c) such other Party makes an assignment for the benefit of, or an arrangement or composition generally with, its creditors, (d) such other Party appoints an examiner of or a receiver or trustee over all or substantially all of its property or suffers the appointment of such party that is not discharged within [***] after such filing or appointment, (e) such other Party proposes a written agreement of composition or extension of its debts, (f) such other Party proposes or is a party to any dissolution, liquidation or winding up or (g) such other Party admits in writing its inability generally to meet its obligations as they fall due in the ordinary course.

14.6.2 **Section 365(n) Rights**. For purposes of Section 365(n) of the Code and any similar Applicable Law, foreign or domestic, all rights and licenses granted under or pursuant to any Section of this Agreement are rights to "intellectual property" (as defined in Section 101(35A) of the Code). The Parties agree that the licensee of such rights under this Agreement will retain and may fully exercise all of its protections, rights and elections under the Code and any similar laws in any other country. Without limiting the generality of the foregoing, the Parties intend and agree that any sale of the licensor's assets under Section 363 of the Code will be subject to the licensee's rights under Section 365(n) of the Code, that the licensee cannot be compelled to accept a money satisfaction of its interests in the intellectual property licensed pursuant to this Agreement and that any such sale therefore may not be made to a purchaser "free and clear" of the licensee's rights under this Agreement and Section 365(n) of the Code without the express, contemporaneous consent of the licensee. Further, each Party agrees and acknowledges that all payments by the licensee to the licensor hereunder, other than the Royalty Payments pursuant to Section

9.3.1 (*Royalty Payments*), do not constitute royalties within the meaning of Section 365(n) of the Bankruptcy Code or relate to licenses of intellectual property hereunder. The licensor will, during the Term, create and maintain current copies or, if not amenable to copying, detailed descriptions or other appropriate embodiments, to the extent feasible, of all such intellectual property. Each Party hereby acknowledges and agrees that "embodiments" of intellectual property within the meaning of Section 365(n) of the Code include copies of research data, laboratory samples, product samples and inventory, formulas, laboratory notes and notebooks, pre-clinical research data and results, tangible Know-How and rights of access or reference, in each case, that relate to such intellectual property. If (a) a case under the Code is commenced by or against the licensor, (b) this Agreement is rejected as provided in the Code and (c) the licensee elects to retain its rights hereunder as provided in Section 365(n) of the Code, then the licensor (in any capacity, including debtor-in-possession) and its successors and assigns (including a trustee) will: (i) provide to the licensee all such intellectual property (including all embodiments thereof) held by the licensor and such successors and assigns, or otherwise available to them, immediately upon the licensee's written request; and (ii) not interfere with the licensee's rights under this Agreement, or any agreement supplemental hereto, to such intellectual property (including such embodiments), including any right to obtain such intellectual property (or such embodiments) from another entity, to the extent provided in Section 365(n) of the Code. Whenever the licensor or any of its successors or assigns provides to the licensee any of the intellectual property licensed hereunder (or any embodiment thereof) pursuant to this Section 14.6.2 (*Section 365(n) Rights*), the licensee will have the right to perform the licensor's obligations hereunder with respect to such intellectual property, but neither such provision nor such performance by the licensee will release the licensor from liability resulting from rejection of the license or the failure to perform such obligations. The provisions of this Section 14.6.2 (*Section 365(n) Rights*) are without prejudice to any rights the licensee may have arising under the Code, the laws of other jurisdictions governing insolvency and bankruptcy or other Applicable Law. The Parties agree that they intend the rights, powers and remedies set forth in this Section 14.6.2 (*Section 365(n) Rights*), including: (a) the licensee's right of access to any intellectual property (including all embodiments thereof) of the licensor, or any Third Party with whom the licensor contracts to perform an obligation of such licensor under this Agreement which is necessary for the Development, Manufacture, Commercialization or other Exploitation of a Licensed Product; (b) the right to contract directly with any Third Party described in clause (a) of this Section 14.6.2 (*Section 365(n) Rights*) to complete the contracted work; and (c) the right to cure any breach of or default under any such agreement with a Third Party and set off the costs thereof against amounts payable to the licensor under this Agreement, in each case ((a) through (c)): (i) to extend to the maximum extent permitted by Applicable Law, including for purposes of the Code and any similar laws in any other country; (ii) to be enforceable; and (iii) to be additional to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in equity (including pursuant to the Code and any similar laws in any other country).

14.7 Full Force and Effect During Notice Period. This Agreement will remain in full force and effect until the expiration of the applicable termination notice period. For clarity, if Sanofi or any of its Affiliates or Sublicensees achieve any Milestone Events during the termination notice period, then the corresponding Milestone Payment is accrued and Sanofi will remain responsible for the payment of such Milestone Payment even if the due date of such Milestone Payment occurs after the effective date of the termination.

14.8 Effects of Termination. In the event of any termination of this Agreement the following will apply with respect to the Terminated Products; *provided* that in the event of termination by Sanofi pursuant to Section 14.6 (*Termination for Insolvency*), only Section 14.8.4 (*Inventory*), Section 14.8.5 (*Clinical Trials*), Section 14.8.8 (*Termination of Rights*), and Section 14.8.9 (*Return of Confidential Information*) shall apply to such termination:

14.8.1 **Reversion**. In the event that Fulcrum notifies Sanofi in writing (such notice, a "**Reversion Notice**") on or before the [***] following the termination of this Agreement with respect to any Terminated Product that it wishes to obtain a reversion license to (such Terminated Products, "**Reversion Products**"), the following provisions will apply:

(a) **License Grant**.

(i) Fulcrum will have, and Sanofi hereby grants to Fulcrum, effective upon such termination, a worldwide, exclusive, perpetual, and sublicensable (through multiple tiers) license under (1) all Sanofi Background Technology that is actually used in the Reversion Products in the Terminated Regions as of the effective date of termination or otherwise Covers the Reversion Product as it was being Exploited in the Terminated Region as of the effective date of termination (whether in the Global Development Plan or Sanofi Independent Development Plan) and (2) Sanofi's interest in the Collaboration Technology that is necessary or reasonably useful for the Exploitation of the Reversion Products in the Terminated Regions, in each case (1) and (2), other than any Sanofi Manufacturing Technology that is *not* necessary to perform the Manufacturing process transferred under Section 14.8.1(b) (*Manufacturing Technology Transfer*) ("**Sanofi Reversion Technology**") solely to Exploit the Reversion Products in the Terminated Regions (the "**Reversion License**"), *provided*, that if this Agreement is terminated by Sanofi pursuant to Section 14.4 (*Termination by Sanofi for Safety*), (A) the Sanofi Reversion Technology shall not include any Patent Rights or Know-How, the practice of which was, or was reasonably believed to be, causally related to the applicable safety concern, and (B) the Reversion License shall not include the right to Exploit any Licensed Product in the manner that was, or was reasonably believed to be, causally related to the applicable safety concern.

(ii) The Reversion License will be (1) royalty-free if this Agreement is terminated by Fulcrum pursuant to Section 14.2 (*Termination for Material Breach*) and (2) royalty-bearing in all other events of termination, on financial terms reflecting reasonable financial compensation and fair market value of such license, determined in accordance with customary industry practice. If, in the event this Agreement is terminated by Sanofi pursuant to Section 14.2 (*Termination for Material Breach*), Section 14.3 (*Termination by Sanofi for Convenience*) or Section 14.4 (*Termination by Sanofi for Safety*) or by Fulcrum pursuant to Section 14.5 (*Termination by Fulcrum for Sanofi's Cessation of Development and Commercialization*), and the Parties cannot agree on the financial terms of such license within a period of [***] of the Reversion Notice, then such dispute shall be referred to the Executive Officers of the Parties for resolution. If the Executive Officers do not fully resolve such dispute within [***] (or a later

date agreed to by each of the Parties) of the dispute being referred to them then the financial terms of such license shall be decided by baseball arbitration pursuant to the terms set forth on **Schedule 14.8.1(a)** (*Baseball Arbitration Terms*).

(b) **Manufacturing Technology Transfer**. At Fulcrum's request, Sanofi will promptly, at Sanofi's discretion, (i) transfer the last Manufacturing process for the Reversion Product that may contain proprietary Manufacturing Know-How of Sanofi or its Affiliates (determined at Sanofi's discretion) to a CMO of Sanofi's choice and reasonably acceptable to Fulcrum, *provided* that Sanofi may exclude proprietary Know-How embedded in the existing Manufacturing process from direct transfer to Fulcrum and such CMO agrees to keep such Manufacturing process confidential and not transfer such proprietary Know-How directly or indirectly to Fulcrum; (ii) transfer to Fulcrum or to a CMO mutually agreed by the Parties (such mutual agreement of Sanofi not to be unreasonably withheld, conditioned or delayed), the last Manufacturing process for the Reversion Product used by Sanofi that does not include proprietary Manufacturing Know-How of Sanofi or its Affiliates (determined at Sanofi's discretion); or (iii) at Sanofi's sole cost use Commercially Reasonable Efforts to develop (by itself or through a CMO reasonably acceptable to Fulcrum, such acceptance not to be unreasonably withheld, conditioned or delayed), an alternative Manufacturing process for the Reversion Product that excludes proprietary Manufacturing Know-How of Sanofi or its Affiliates, and to conduct a technology transfer of such alternative process to Fulcrum or a CMO mutually agreed by the Parties (such mutual agreement not to be unreasonably withheld, conditioned or delayed). Such Manufacturing process technology transfer, in such cases ((i)-(iii)), will be at Fulcrum's sole cost pursuant to a budget to be mutually agreed upon by the Parties unless the applicable termination of this Agreement is by Fulcrum pursuant to Section 14.2 (*Termination for Material Breach*) or by Sanofi pursuant to Section 14.3 (*Termination by Sanofi for Convenience*), in which case it shall be at Sanofi's sole cost pursuant to a budget to be mutually agreed upon by the Parties. Sanofi shall, and where applicable, cause its Affiliates or CMOs to supply Reversion Product in bulk finished form, to Fulcrum pursuant to the terms of a supply agreement (to be promptly negotiated by the Parties on commercially reasonable terms) on a cost plus [***] basis, for a period from the effective date of such termination until such time as Sanofi shall have performed all of its obligations pursuant to the foregoing clauses (i) through (iii), as applicable; *provided* that, if Sanofi elects to develop an alternative Manufacturing process for the Reversion Product that excludes proprietary Manufacturing Know-How of Sanofi or its Affiliates, then, *provided* that Fulcrum uses Commercially Reasonable Efforts to obtain qualification to Manufacture the Reversion Product, Sanofi will continue to supply Fulcrum with Reversion Product in bulk finished form until Fulcrum or a CMO obtains such qualification to Manufacture the Reversion Product using such alternative Manufacturing process. In the event the Parties are unable to agree on either the budget for such Manufacturing process technology transfer, or the terms of such supply agreement, within [***] following Sanofi's receipt of a request from Fulcrum to negotiate such budget or supply agreement (as applicable), then upon notice to Sanofi, such budget or the final terms of such supply agreement, as applicable, shall immediately be referred for resolution in accordance with Section 15.1 (*Dispute Resolution*).

14.8.2 **Sanofi Product Trademarks**.

(a) **License Grant**. Effective as of the effective date of termination of this Agreement with respect to a Terminated Product, Sanofi hereby grants to Fulcrum an exclusive, transferable (pursuant to Section 16.1 (*Assignment*)) and sublicensable (through multiple tiers) license under any Sanofi Product Trademarks that are actually used in, and solely related to, the Commercialization of the Terminated Products as of the effective date of termination of this Agreement with respect to such Terminated Product in the Terminated Region, solely as necessary to Commercialize the Terminated Products in the Terminated Region.

(b) **Quality Control**. In connection with the license grant to the Sanofi Product Trademarks described in Section 14.8.2(a)14.8.2(a) (*License Grant*), Fulcrum covenants that all uses of the Sanofi Product Trademarks, and the Terminated Products offered in connection therewith, by or on behalf of Fulcrum, its Affiliates or sublicensees, shall be consistent with (i) the high quality of the Terminated Products being offered under the Sanofi Product Trademarks as of the effective date of termination, and (ii) any quality standards or practices required under Applicable Law. Upon Sanofi's or its designee's reasonable request, Fulcrum shall provide samples of any Terminated Products or related goods and services bearing the Sanofi Product Trademarks to Sanofi or its designee for the purpose of inspecting and evaluating Fulcrum's compliance with the requirements set forth in this Section14.8.2(b) 14.8.2(b) (*Quality Control*).

14.8.3 **Regulatory Submissions and Regulatory Approvals**. Sanofi will and hereby does, and will cause its Affiliates and Sublicensees to, (a) within a reasonable period of time after the effective date of termination of this Agreement with respect to a Terminated Product, assign and transfer to Fulcrum or its designee all of Sanofi's rights, title, and interests in and to all Regulatory Submissions, Regulatory Approvals, and Reimbursement Approvals (excluding the drug master file or equivalent maintained by Sanofi, its Affiliates, Sublicensees or subcontractors) then Controlled by Sanofi or any of its Affiliates or Sublicensees, in each case, solely related to such Terminated Products, *provided*, that Sanofi will have the right to redact and remove from such Regulatory Submissions, Regulatory Approvals and Reimbursement Approvals any business sensitive information of Sanofi, its Affiliates, Sublicensees or subcontractors contained in such Regulatory Submissions, Regulatory Approvals and Reimbursement Approvals, and (b) to the extent assignment pursuant to clause (a) is delayed or is not permitted by the applicable Regulatory Authority, permit Fulcrum to cross-reference and rely upon any such Regulatory Submissions, Regulatory Approvals, and Reimbursement Approvals (excluding (i) the drug master file or equivalent maintained by Sanofi, its Affiliates, Sublicensees or subcontractors and (ii) any business sensitive information of Sanofi, its Affiliates, Sublicensees or subcontractors, in each case (i) or (ii), contained in such Regulatory Submissions, Regulatory Approvals, and Reimbursement Approvals) filed by Sanofi or any of its Affiliates or Sublicensees solely in connection with the Research, Development, Manufacture, Commercialization or other Exploitation of the Terminated Products. Sanofi will execute and deliver, or will cause to be executed and delivered, to Fulcrum or its designee such endorsements, assignments, commitments, acknowledgements, and other documents as may be necessary and reasonably requested by Fulcrum to assign, convey, transfer, and deliver to Fulcrum or its designee all of Sanofi's or its applicable Affiliate's or designee's rights, title, and interests in and to all such assigned Regulatory Submissions, Regulatory Approvals, and Reimbursement Approvals,

including submitting to each applicable Regulatory Authority or other Governmental Authority in the Terminated Regions a letter or other necessary documentation (with copy to Fulcrum) notifying such Regulatory Authority or other Governmental Authority of, or otherwise giving effect to, the transfer of ownership to Fulcrum of all such assigned Regulatory Submissions, Regulatory Approvals, and Reimbursement Approvals.

14.8.4 **Inventory**. Upon any termination of this Agreement with respect to a Terminated Product, Sanofi will be entitled, for a period of [***] after the effective date of termination, to: (a) complete Manufacture of work-in-progress of such Terminated Products and (b) continue conducting Commercialization activities with respect to such Terminated Products in Sanofi's inventory as of such effective date of termination (or added to such inventory as a result of the completion of Manufacturing activities described in clause (a)). During such [***] inventory sell-off period, the terms of Article 9 (*Payments*) will continue to apply to any Commercialization activities conducted by or on behalf of Sanofi pursuant to the foregoing clause (b). At the end of such [***] inventory sell-off period, at Fulcrum's election and request, Sanofi will transfer to Fulcrum or its designee some or all inventory of the Terminated Products for the Terminated Regions then in the possession or Control of Sanofi, its Affiliates or Sublicensees; *provided* that Fulcrum will pay Sanofi a price equal to [***] of Sanofi's Manufacturing Cost for such Terminated Product.

14.8.5 **Clinical Trials**. If as of the effective date of termination of this Agreement with respect to a Terminated Product, any Clinical Trials of such Terminated Product are being conducted by or on behalf of Sanofi or its Affiliates, then within a reasonable period after such effective date of termination, Sanofi and its Affiliates will wind down any such ongoing Clinical Trials pursuant to Applicable Law or any requirements from the applicable Regulatory Authorities unless Fulcrum elects to assume such ongoing Clinical Trials after such effective date of termination, in which case: (a) to the extent permitted by Applicable Law and any requirements from the applicable Regulatory Authorities, Sanofi and its Affiliates will transfer such Clinical Trials to Fulcrum at Fulcrum's sole cost and expense; and (b) Fulcrum will assume any and all liabilities for the conduct of such transferred Clinical Trials for the applicable Terminated Product as of the effective date of such transfer.

14.8.6 **Transition Services Agreement**. Upon written request from Fulcrum to Sanofi provided within [***] of the effective date of termination of this Agreement with respect to a Terminated Product, the Parties will enter into good-faith negotiations for up to [***] for a definitive transition services agreement to facilitate the orderly transition to Fulcrum or its designee of all Commercialization and other activities then being performed by or on behalf of Sanofi or its Affiliates or Sublicensees for the Terminated Products and any other transition or assistance mutually agreed upon by the Parties (the "**Transition Services Agreement**"). The Transition Services Agreement will (a) be on reasonable market terms and (b) include reimbursement by Fulcrum to Sanofi for Sanofi's Internal Costs and External Costs, in each case, of providing any such transition assistance to Fulcrum. In addition, neither Party may unreasonably withhold, delay or condition their consent to the execution of the Transition Services Agreement. If the Parties cannot agree on the financial terms of such Transition Services Agreement within the [***] time period, then such dispute shall be referred to the Executive Officers of the Parties for resolution. If the Executive Officers do not fully resolve such dispute within [***] (or a later date agreed to by each of the Parties) of the dispute being referred to them, then, to the extent the dispute pertains to [***] of such Transition Services Agreement, such dispute shall be decided by

baseball arbitration pursuant to the terms set forth on **Schedule 14.8.1(a)** (*Baseball Arbitration Terms*).

14.8.7 **Termination by Sanofi for Breach**. Notwithstanding any provision to the contrary in this Section 14.8 (*Effects of Termination*), in the event of any termination of this Agreement with respect to a Terminated Product by Sanofi pursuant to Section 14.2 (*Termination for Material Breach*), Fulcrum will be responsible for the reasonable out-of-pocket costs incurred by Sanofi directly in connection with the performance of the activities set forth in this Section 14.8 (*Effects of Termination*). Sanofi will invoice Fulcrum quarterly for the foregoing costs incurred by or on behalf of Sanofi in such Calendar Quarter, and Fulcrum will pay the undisputed invoiced amounts within [***] after the date of any such invoice.

14.8.8 **Termination of Rights**. Upon any termination of this Agreement in its entirety or with respect to a Terminated Product in a Terminated Region, all rights licensed to each Party under this Agreement will terminate, including all sublicenses granted by Sanofi or its Affiliates pursuant to Section 2.3.1 (*Rights of Sanofi to Grant Sublicenses*), with respect to such Terminated Product in such Terminated Region, as applicable, *except* (a) as set forth in Section 2.3.2 (*Effects of Termination on Sanofi Sublicenses to a Third Party*) or (b) with respect to the licenses granted in Section 2.2.3 (*License Grants to Fulcrum*), but, for clarity, (i) such termination will not affect the Parties' rights and obligations under this Agreement with respect to other Licensed Products or other Regions for which this Agreement has not terminated and (ii) Fulcrum's royalty obligation with respect to such licenses in Section 2.2.3 (*License Grants to Fulcrum*) will survive until and unless such license subsequently terminates. Notwithstanding the foregoing, each Party will retain its joint ownership interests in the Joint Collaboration Technology.

14.8.9 **Return of Confidential Information**. If this Agreement is terminated in its entirety, then each Party will return or destroy (at the other Party's election) all Confidential Information of the other Party in its possession upon termination of this Agreement at the Disclosing Party's election and written request and, if applicable, the Receiving Party will provide a written confirmation of such destruction within [***] of such request. Notwithstanding the foregoing or any provision to the contrary set forth in this Agreement: (a) the foregoing terms of this Section 14.8.9 (*Return of Confidential Information*) will not apply to any Confidential Information that is necessary to allow the Receiving Party to perform its obligations or exercise any of its rights that expressly survive the applicable termination of this Agreement, and the Receiving Party may retain one copy of such Confidential Information for its legal archives; and (b) the Receiving Party will not be required to destroy electronic files containing such Confidential Information that are made in the ordinary course of its business information back-up procedures pursuant to its electronic record retention and destruction practices that apply to its own general electronic files and information.

14.9 Survival; Accrued Rights. Except as otherwise expressly set forth in this Agreement, the expiration or termination of this Agreement will not relieve the Parties of any liability that accrued hereunder prior to the effective date of such expiration or termination nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement, nor prejudice either Party's right to obtain performance of any obligation. Without limiting the foregoing, the following provisions of this Agreement will survive the expiration or termination of this Agreement: Article 1 (*Definitions*) to the extent the definitions are used in other provisions surviving the expiration or termination of this Agreement; Section 2.2.3 (*License Grants to Fulcrum*) (*provided* that Section 2.2.3(a) will no longer be restricted to the

Global Development Plan and Fulcrum Independent Development Plan but will also include all Research or Development activities that are solely intended to support obtaining or maintaining Regulatory Approval or label expansion of the Terminated Products in the Fulcrum Territory in the event of termination but not expiration of this Agreement); Section 2.4 (*No Other Rights and Retained Rights*); Sections 9.3 (*Royalties*) through 9.12 (*Late Payments; Disputed Payments*) solely to the extent that any payment accrued prior to the effective date of expiration or termination of this Agreement or with respect to royalties payable as a result of Fulcrum's license grant under Section 2.2.3 (*License Grants to Fulcrum*) or the reversion royalties under Section 14.8.1 (*Reversion*), and with respect to record keeping obligations under Section 9.7.1 (*Financial Records*), solely for the time periods set forth therein; Section 10.1.1 (*Ownership of Background Technology*); Section 10.1.2 (*Ownership of Foreground Intellectual Property*); the last sentence of Section 11.3.7 (*Debarred/Excluded Persons*), Article 13 (*Indemnification*) (*provided* that Section 13.4 (*Insurance*) shall survive solely for the time period set forth therein); Article 12 (*Confidentiality*) solely for the period set forth therein (*provided* that, in the event of termination but not expiration of this Agreement, notwithstanding Section 12.2 (*Confidential Information*), all Fulcrum Know-How will be deemed the Confidential Information of Fulcrum rather than the Confidential Information of both Parties upon completion of Sanofi's transition activities under Section 14.8 (Effects of Termination) of this Agreement) and *except* for Section 12.5 (*Joint Publication Strategy*), Section 12.6 (*Publication and Listing of Clinical Trials*) and Section 12.7.1 (*Press Releases*), which will each terminate upon expiration or termination of this Agreement; the second sentence of Section 14.1 (*Term*); Section 14.8 (*Effects of Termination of this Agreement*); this Section 14.9 (*Survival; Accrued Rights*); Article 15 (*Dispute Resolution; Governing Law*); and Article 16 (*Miscellaneous*). For any surviving provisions requiring action or decision by a Committee, each Party shall appoint representatives to act as its Committee members. All provisions not surviving in accordance with the foregoing shall terminate upon expiration or termination of this Agreement and be of no further force and effect. If this Agreement is terminated with respect to one or more Reversion Products but not in its entirety, then following such termination the foregoing provisions of this Agreement shall remain in effect with respect to such Reversion Product(s) (to the extent they would survive and apply in the event this Agreement expires or is terminated in its entirety), and all provisions not surviving in accordance with the foregoing shall terminate upon termination of this Agreement with respect to the applicable Reversion Products and be of no further force and effect.

ARTICLE 15
DISPUTE RESOLUTION; GOVERNING LAW

15.1 Dispute Resolution.

15.1.1 Each Party will ensure that an Executive Officer is designated for such Party at all times during the Term for dispute resolution purposes, and will promptly notify the other Party of any change in its designated Executive Officer. Except as expressly set forth in this Agreement, in the event of a dispute arising under, relating to, or in connection with this Agreement (except for disputes arising at the JSC, which will be resolved in accordance with Section 3.8 (*Resolution of Committee Disputes*)), the Alliance Manager of the Party claiming that such dispute exists will give notice in writing (a "**Notice of Dispute**") to the other Party of the nature of the dispute. For [***] after receipt of such Notice of Dispute, the Parties will make good faith efforts to resolve the dispute ("**EO Dispute Resolution Period**"), and within [***] following receipt of a Notice of Dispute, the Executive Officers will meet (including via teleconference) at a mutually agreed upon time and location for discussion and potential resolution. After the EO Dispute Resolution Period, if the Party that issued the Notice of Dispute considers the dispute to be unresolved, then such Party

may give a written notice to the other Party (a "**Notice of Arbitration**") of the first Party's intent to arbitrate such dispute. If the Party that issued the Notice of Dispute fails to issue a Notice of Arbitration within [***] after the expiration of the EO Dispute Resolution Period, then such dispute will be deemed to have been resolved under this Section 15.1.1 (*Dispute Resolution*).

15.1.2 Any dispute (other than any dispute described in Section 15.2 (*Intellectual Property Disputes*) below) unresolved under Section 15.1.1 (*Dispute Resolution*) shall be finally resolved by binding arbitration administered by the Judicial Arbitration and Mediation Services ("**JAMS**") pursuant to JAMS' Streamlined Arbitration Rules and Procedures then in effect, as modified in this Section 15.1 (*Dispute Resolution*) (the "**JAMS Rules**"), except to the extent such JAMS Rules are inconsistent with this Section 15.1 (*Dispute Resolution*) in which case, this Section 15.1 (*Dispute Resolution*) will control (including with regard to any limitations of liability or forms of relief).

15.1.3 The applicable dispute will be resolved by final and binding arbitration before a single arbitrator mutually agreed by the Parties; *provided*, *however*, that if the Parties cannot agree within [***] after receipt of a notice to arbitrate, then the arbitrator will be chosen in accordance with JAMS Rule 15 (the "**Arbitrator**"). The Arbitrator (i) will not be from academia, (ii) will be a qualified attorney in private practice or a retired judge with experience in complex commercial disputes, (iii) will be professionally fluent in English, (iv) will have not less than [***] of experience in the biotechnology or pharmaceutical industry and subject matter expertise with respect to the matter subject to arbitration, and (v) will have educational training and industry experience sufficient to demonstrate a reasonable level of scientific, financial, medical and industry knowledge relevant to the particular dispute. The Arbitrator will agree to a fixed fee of [***] or less; if the Arbitrator will not agree to such amount, then either Party will have the right to cause a different Arbitrator to be selected.

15.1.4 Discovery will be limited to [***] custodial document productions per side, and no more than [***] discovery depositions may be conducted per side.

15.1.5 Direct testimony per fact witness will not exceed [***] hours, and cross examination of any fact witness will not exceed [***].

15.1.6 The JAMS Rules will be modified to delete paragraphs 16.2(b) and 16.2(e) of such procedures as in effect on the Effective Date, and the timelines will be modified to provide that: (i) the discovery cutoff for percipient discovery will not exceed [***] after the preliminary conference, (ii) the discovery cutoff for expert discovery will not exceed [***] after the preliminary conference and (iii) the hearing will commence within [***] after the cutoff for expert discovery and will be concluded within [***] after it is commenced.

15.1.7 The Arbitrator will, within [***] after the conclusion of the hearing, issue a written award and statement of decision describing the material facts and the grounds for the conclusions on which the award is based, including the calculation of any damages awarded. The Arbitrator will be authorized to award compensatory damages, but will not be authorized to reform, modify or materially change this Agreement. The proceedings and decisions of the Arbitrator will be confidential, final and binding on the Parties, and judgment upon the award of the Arbitrator may be entered in any court having jurisdiction thereof. For clarity, neither Party will have any right to appeal the decisions of the Arbitrator.

15.1.8 Each Party will bear its own costs and expenses (including legal fees and expenses) relating to the arbitration proceeding, except that the fees of the Arbitrator and other related costs of the arbitration will be shared equally by the Parties, unless the Arbitrator determines that a Party has incurred unreasonable expenses due to vexatious or bad faith positions taken by the other Party, in which event the Arbitrator may make an award of all or any portion of such expenses (including legal fees and expenses) so incurred.

15.1.9 The Arbitrator will be required to render the decision in writing that is no more than [***] pages. The Arbitrator will comply with, and the award will be limited by, any express provisions of this Agreement relating to damages or the limitation thereof. The Arbitrator will not have the power to award punitive damages under this Agreement regardless of whether any such damages are contained in a proposal, and such award is expressly prohibited.

15.1.10 Unless the Parties otherwise agree in writing, during the period of time that any arbitration proceeding is pending under this Agreement: (i) the Parties will continue to comply with all those terms and provisions of this Agreement that are not the subject of the pending arbitration proceeding; (ii) in the event the arbitration proceeding concerns a potential material breach under Section 14.2 (*Termination for Material Breach*), the applicable cure period will be stayed until the conclusion of the proceedings under this Section 15.1 (*Dispute Resolution*); and (iii) in the event that the subject of the dispute relates to the exercise by a Party of a termination right hereunder, including in the case of a material breach of this Agreement, the effectiveness of such termination will be stayed until the conclusion of the proceedings under this Section 15.1 (*Dispute Resolution*). All arbitration proceedings and decisions of the Arbitrator under this Section 15.1 (*Dispute Resolution*) will be deemed Confidential Information of both Parties under Article 12 (*Confidentiality*).

15.1.11 The arbitration proceedings will take place in New York City, New York, in the English language.

15.1.12 Nothing in this Section 15.1 (*Dispute Resolution*) will preclude either Party from seeking equitable relief or interim or provisional relief from a court of competent jurisdiction, including a temporary restraining order, preliminary injunction or other interim equitable relief, concerning a dispute either prior to or during any arbitration if necessary to protect the interests of such Party or to preserve the status quo pending the arbitration proceeding.

15.1.13 In the event of a dispute regarding any payments owing under this Agreement, all undisputed amounts will be paid promptly when due and the balance, if any, promptly after resolution of the dispute.

15.2 Intellectual Property Disputes. Notwithstanding any provision to the contrary set forth in this Agreement, if a dispute arises under this Agreement with respect to the validity, scope, enforceability, or ownership of any Patent Right or other intellectual property rights, and such dispute is not resolved in accordance with Section 3.8.1 (*Referral to Executive Officers*), then such dispute will be submitted to a court of competent jurisdiction in the jurisdiction in which such Patent Right or other intellectual property right was granted or arose.

15.3 Equitable Remedies. Notwithstanding any provision to the contrary set forth in this Agreement, the Parties each stipulate and agree that (a) the other Party's Confidential Information includes highly sensitive trade secret information such that a breach of Article 12 (*Confidentiality*) by a Party will cause irrevocable harm for which monetary damages would not provide a sufficient

remedy; and (b) in such case of such breach of Article 12 (*Confidentiality*), the non-breaching Party will be entitled to equitable relief, including specific performance, temporary or permanent restraining orders, preliminary injunction, permanent injunction, or other equitable relief without the posting of any bond or other security, from any court of competent jurisdiction. In addition, and notwithstanding any provision to the contrary set forth in this Agreement, in the event of any other actual or threatened breach hereunder, the aggrieved Party may seek equitable relief (including specific performance, temporary or permanent restraining orders, or other equitable relief) from any court of competent jurisdiction without first submitting to the dispute resolution procedures set forth in Article 15 (*Dispute Resolution; Governing Law*).

15.4 Governing Law; English Language. This Agreement and all amendments, modifications, alterations, or supplements hereto, and the rights of the Parties, will be construed under and governed by the laws of the State of New York, United States, exclusive of its conflicts of laws principles. The provisions of the United Nations Convention on Contracts for the International Sale of Goods will not apply to this Agreement or any subject matter hereof. This Agreement has been prepared in the English language and the English language will control its interpretation. All consents, notices, reports, and other written documents to be delivered or provided by a Party under this Agreement will be in the English language, and in the event of any conflict between the provisions of any document and the English language translation thereof, the terms of the English language translation will control.

15.5 Waiver of Jury Trial. TO THE EXTENT NOT PROHIBITED BY APPLICABLE LAW THAT CANNOT BE WAIVED, THE PARTIES HEREBY WAIVE, AND COVENANT THAT THEY WILL NOT ASSERT (WHETHER AS PLAINTIFF, DEFENDANT, OR OTHERWISE), ANY RIGHT TO TRIAL BY JURY IN ANY ACTION ARISING IN WHOLE OR IN PART UNDER OR IN CONNECTION WITH THIS AGREEMENT, WHETHER NOW EXISTING OR HEREAFTER ARISING, AND WHETHER SOUNDING IN CONTRACT, TORT, OR OTHERWISE. THE PARTIES AGREE THAT ANY OF THEM MAY FILE A COPY OF THIS PARAGRAPH WITH ANY COURT AS WRITTEN EVIDENCE OF THE KNOWING, VOLUNTARY, AND BARGAINED-FOR AGREEMENT AMONG THE PARTIES IRREVOCABLY TO WAIVE ITS RIGHT TO TRIAL BY JURY IN ANY PROCEEDING WHATSOEVER BETWEEN THEM RELATING TO THIS AGREEMENT, WHICH WILL INSTEAD BE TRIED IN A COURT OF COMPETENT JURISDICTION BY A JUDGE SITTING WITHOUT A JURY.

ARTICLE 16
MISCELLANEOUS

16.1 Assignment. This Agreement may not be assigned or otherwise transferred, whether by operation of law or otherwise, nor may any right or obligation hereunder be assigned or transferred, by either Party without the prior written consent of the other Party. Notwithstanding the foregoing, (a) Fulcrum may assign its rights to receive any of the Royalty Payments or Milestone Payments owed under Article 9 (*Payments*) to a Third Party (such assignment, a "**Securitization Transaction**"), *provided* that in connection with such a Securitization Transaction, Fulcrum does not make such Third Party a third party beneficiary of this Agreement or otherwise give such Third Party any right to directly enforce any provisions of this Agreement against Sanofi or its Affiliates, and (b) either Party may, without consent of the other Party, assign this Agreement and its rights and obligations hereunder in whole or in part (i) to its successor-in-interest in connection with the transfer or sale of all or substantially all of its assets, or (ii) to its successor-in-interest in a merger, acquisition, or similar transaction or series of related transactions. In the event of an assignment pursuant to the foregoing clauses (b)(i) or (b)(ii), such assignment will only be effective if the Person to whom this

Agreement is assigned agrees in writing to assume all of the assigning Party's obligations under this Agreement and the assigning Party provides written notice of such assignment to the non-assigning Party within [***] after the effective date of such assignment. In addition, Sanofi will have the right, without the consent of Fulcrum: (A) to perform any or all of its obligations and exercise any or all of its rights under this Agreement through any of its Affiliates or Sublicensees; and (B) to assign any or all of its rights and delegate any or all of its obligations hereunder to any of its Affiliates or Sublicensees or to any successor-in-interest (whether by merger, acquisition or otherwise) to all or substantially all of the business to which this Agreement (or the applicable Licensed Product(s)) relates; *provided* that Sanofi will provide written notice to Fulcrum within [***] after such assignment or delegation. Any attempted assignment of this Agreement in violation of this Section 16.1 (*Assignment*) will be null, void, and of no legal effect. Any permitted assignee will expressly assume in writing all assigned obligations of its assignor under this Agreement. This Agreement will be binding on and will inure to the benefit of the permitted successors and assigns of the Parties.

16.2 Entire Agreement; Amendment. This Agreement, together with all exhibits and schedules attached hereto, constitutes the entire agreement between the Parties with respect to the subject matter hereof, and supersedes and merges all prior and contemporaneous, express or implied agreements, negotiations, representations, and understandings, either oral or written, regarding the same, (including that certain confidentiality agreement between the Parties dated November 17, 2021 and as amended on November 17, 2022 ("**Confidential Disclosure Agreement**")). All information shared by the Parties pursuant to the Confidential Disclosure Agreement will be Confidential Information under this Agreement from and after the Effective Date, and the use and disclosure thereof will be governed by Article 12 (*Confidentiality*). This Agreement may not be modified or amended, except by another agreement in writing executed by duly authorized signatories of each Party.

16.3 No Strict Construction; Interpretation. This Agreement has been prepared jointly and will not be strictly construed against either Party. Ambiguities, if any, in this Agreement will not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision. Except where the context expressly requires otherwise, (a) whenever any provision of this Agreement uses the term "including" (or "includes"), such term will be deemed to mean "including without limitation" and "including but not limited to" (or "includes without limitations" and "includes but is not limited to") regardless of whether the words "without limitation" or "but not limited to" actually follow the term "including" (or "includes"); (b) "herein," "hereby," "hereunder," "hereof," and other equivalent words will refer to this Agreement in its entirety and not solely to the particular portion of this Agreement in which any such word is used; (c) all definitions set forth herein will be deemed applicable whether the words defined are used herein in the singular or the plural; (d) wherever used herein, any pronoun or pronouns will be deemed to include both the singular and plural and to cover all genders; (e) the recitals set forth at the start of this Agreement, along with the schedules and exhibits to this Agreement, and the terms and conditions incorporated in such recitals and schedules and exhibits will be deemed integral parts of this Agreement and all references in this Agreement to this Agreement will encompass such recitals and schedules and exhibits and the terms and conditions incorporated in such recitals and schedules and exhibits; *provided* that in the event of any conflict between the terms and conditions of this Agreement and any terms and conditions set forth in the recitals, schedules, or exhibits, the terms of this Agreement will control; (f) in the event of any conflict between the terms and conditions of this Agreement and any terms and conditions that may be set forth on any order, invoice, verbal agreement, or otherwise, the terms and conditions of this Agreement will govern; (g) unless otherwise provided, all references to Sections, Articles, and Schedules in this Agreement

are to Sections, Articles, and Schedules of and to this Agreement; (h) any reference to any federal, national, state, local, or foreign statute or law will be deemed to also refer to all rules and regulations promulgated thereunder, and any reference to any law, rule, or regulation will be deemed to include the then-current amendments thereto or any replacement or successor law, rule, or regulation thereof; (i) wherever used, the word "shall" and the word "will" are each understood to be imperative or mandatory in nature and are interchangeable with one another; (j) the term "or" will be interpreted in the inclusive sense commonly associated with the term "and/or"; (k) references to a particular Person include such Person's successors and assigns to the extent not prohibited by this Agreement; (l) the section headings and captions used herein are inserted for convenience of reference only and will not be construed to create obligations, benefits, or limitations; (m) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented, or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein); (n) the word "notice" means notice in writing (whether or not specifically stated) and will include notices, consents, approvals and other written communications contemplated under this Agreement; and (o) provisions that require that a Party, the Parties or any committee hereunder "agree," "consent," or "approve" or the like will require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes, or otherwise (but excluding e-mail and instant messaging).

16.4 Severability. If any provision of this Agreement is declared invalid by a court of last resort or by any court or other governmental body the decision of which an appeal is not taken within the time provided by law, then and in such event, this Agreement will be deemed to have been terminated only as to the portion thereof that relates to the provision invalidated by that decision and only in the relevant jurisdiction, but this Agreement will remain in force, in all other respects and all other jurisdictions; *provided, however*, that if the provision so invalidated is essential to the Agreement as a whole, then the Parties will negotiate in good faith to amend the terms hereof as nearly as practical to carry out the original intent of the Parties, and, failing such amendment, either Party may submit the matter for resolution pursuant to Article 15 (*Dispute Resolution; Governing Law*).

16.5 Notices. All notices that are required or permitted hereunder will be in writing in English and sufficient if (i) delivered by hand or by prepaid internationally-recognized overnight courier or (ii) sent by first class, registered or certified mail, postage prepaid, return receipt requested, and in each case, addressed as follows (with a courtesy copy sent by email, which will not constitute notice):

If to Fulcrum:

Fulcrum Therapeutics, Inc.
26 Landsdowne Street
Cambridge, MA 02139
Attention: [***]
Email: [***]

If to Sanofi:

Sanofi – Global Alliance Management
450 Water Street
Cambridge, MA 02141
Attention: Global Head of Alliance Management
Email: [***]

With a copy (which will not constitute notice for purposes of this Agreement) to:

Sanofi – Global Business Development
450 Water Street
Cambridge, MA 02141
Attention: [***]
Email: [***]

Sanofi – Legal Global Functions
450 Water Street
Cambridge, MA 02141
Attention: [***]
Email: [***]

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice will be deemed to have been given on the date received, except any notice received after 5:30 p.m. (in the time zone of the receiving Party) on a Business Day or received on a non-Business Day, in each case, will be deemed to have been received on the next Business Day. A Party may add, delete or change the person or address to which notices should be sent at any time upon written notice delivered to the other Parties in accordance with this Section 16.5 (*Notices*). This Section 16.5 (*Notices*) is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Agreement, which communications may be sent by email, including as set forth in Section 3.1.2 (*Membership*), Section 3.2.2 (*Membership of the JDC*), Section 3.3.2 (*Membership of the JMC*), Section 3.4.2 (*Membership of the JCC*), Section 3.5.2 (*Subcommittee Leadership and Meetings*) and Section 3.7.1 (*General Decision-Making Process*).

16.6 Force Majeure. Neither Party will be held liable or responsible to the other Party or be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement if such failure or delay is caused by or results from events beyond the reasonable control of the non-performing Party, including: fires, floods, earthquakes, hurricanes, shortages, epidemics, pandemics, quarantines, war, acts of war (whether war be declared or not), terrorist acts, insurrections, riots, civil commotion, strikes, or other labor disturbances of a Person other than the non-performing Party, acts of God or acts, omissions or delays in acting by any Governmental Authority (except to the extent such omission or delay results from the breach by the non-performing Party or any of its Affiliates of any term or condition of this Agreement) (any such event, a "**Force Majeure Event**"). The non-performing Party will notify the other Party of such Force Majeure Event within [***] after such occurrence by giving notice to the other Party stating the nature of the Force Majeure Event, its anticipated duration and any action being taken to avoid or minimize its effect. The suspension of performance will be of no greater scope and no longer duration than is necessary. The non-performing Party will use commercially reasonable efforts to avoid or remove such Force Majeure Event, to mitigate the effect of such Force Majeure Event and to otherwise remedy its inability to perform. The non-performing Party will continue performance in accordance with the terms of this Agreement whenever such causes are removed. When such circumstances arise, the Parties will negotiate in good faith any modifications of the terms of this Agreement that may be necessary or appropriate in order to arrive at an equitable solution.

16.7 Further Assurances. The Parties agree to reasonably cooperate with each other in connection with any actions required to be taken as part of their respective obligations under this Agreement, and will (a) furnish to each other such further information; (b) execute and deliver to each other such other documents; and (c) do such other acts and things (including working collaboratively to correct any clerical, typographical, or other similar errors in this Agreement), all as the other Party may reasonably request for the purpose of carrying out the intent of this Agreement.

16.8 Performance by Affiliates. Notwithstanding any provision to the contrary set forth in this Agreement, either Party will have the right to perform any or all of its obligations and exercise any or all of its rights under this Agreement through any Affiliate; *provided* that such Party shall at all times remain responsible and liable hereunder for the performance of such Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement and will cause its Affiliates to comply with the provisions of this Agreement in connection with such performance.

16.9 Agency. Neither Party is, nor will be deemed to be an employee, agent, or representative of the other Party for any purpose. Each Party is an independent contractor, not an employee, agent, joint venturer or partner of the other Party. Neither Party will have any express or implied right or authority to speak for, represent, or obligate the other Party in any way without prior written authority from the other Party.

16.10 Binding Effect; No Third Party Beneficiaries or Obligors. As of the Effective Date, this Agreement will be binding upon and inure to the benefit of the Parties and their respective permitted successors and assigns. Except as set forth in Article 13 (*Indemnification*), no Person other than Fulcrum, Sanofi, and their respective permitted successors and assigns hereunder will be deemed an intended beneficiary hereunder, nor have any right to enforce any obligation of any Party to this Agreement, nor will any Person other than Fulcrum and Sanofi and their respective permitted successors and assigns have any obligations to any Party under this Agreement.

16.11 No Waiver. Any omission or delay by either Party 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 other Party, will not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement. Any waiver by a Party of a particular breach or default by the other Party will not operate or be construed as a waiver of any subsequent breach or default by the other Party. No waiver, modification, release or amendment of any obligation under or provision of this Agreement will be valid or effective unless in writing and signed by the Parties.

16.12 Cumulative Remedies. No remedy referred to in this Agreement, including termination of this Agreement, is intended to be exclusive, but each will be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.

16.13 Counterparts. This Agreement may be executed in one or more counterparts, all of which taken together will be regarded as one and the same instrument. Each Party may execute this Agreement in Adobe™ Portable Document Format (PDF) sent by electronic mail. PDF signatures of authorized signatories of the Parties will be deemed to be original signatures, will be valid and binding upon the Parties, and, upon delivery, will constitute due execution of this Agreement.

[Remainder of page intentionally left blank; Signature page follows.]

IN WITNESS WHEREOF, the Parties have executed this Agreement through their duly authorized representatives to be effective as of the Effective Date.

FULCRUM THERAPETUICS INC.		**GENZYME CORPORATION**	
By:	/s/ Alex C. Sapir	By:	/s/ Burcu Eryilmaz
Name:	Alex C. Sapir	Name:	Burcu Eryilmaz
Title:	Chief Executive Officer and President	Title:	Global Head of Rare Diseases Franchise

Schedule 1.61
Existing Third Party IP Agreements

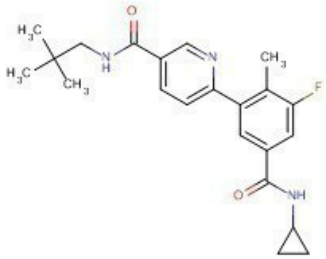
- The GSK License Agreement (as defined in Section 1.104)

- The GSK Side Letter (as defined in Section 1.106)

Schedule 1.83
Fulcrum Patent Rights

[***]

Schedule 1.132
Losmapimod



Formula: $C_{22}H_{26}FN_3O_2$
Molecular Weight: 383.459
GSK Compound Number: GW856553
Fulcrum Compound Number: FTX-1821

Schedule 1.168
Statistical Analysis Plan

[***]

Schedule 4.1
Initial Technology Transfer

[***]

Schedule 5.2
Initial Global Development Plan and Budget

[***]

Schedule 8.2
Supply Agreement Term Sheet

[***]

Schedule 12.7.1
Press Release

Fulcrum Therapeutics Enter into a Collaboration and License Agreement with Sanofi for the Development and Commercialization of Losmapimod in Facioscapulohumeral Muscular Dystrophy

— Sanofi receives exclusive rights to commercialize losmapimod in all territories outside the U.S.; Fulcrum retains full U.S. commercialization rights—

—Fulcrum will receive an upfront payment of $80.0 million, and is eligible to receive $975.0 million in potential milestones, plus royalties on ex-U.S. product sales; parties will share future global development costs 50:50—

— Conference call and webcast scheduled for 8:00 a.m. ET today to discuss the collaboration and other recent corporate developments, in conjunction with first the quarter 2024 financial results—

CAMBRIDGE, Mass., – May 13, 2024 – Fulcrum Therapeutics, Inc.® (Fulcrum) (Nasdaq: FULC), a clinical-stage biopharmaceutical company focused on developing small molecules to improve the lives of patients with genetically defined rare diseases, today announced that it has entered into a collaboration and license agreement with Sanofi (Nasdaq: SNY) for the development and commercialization of losmapimod, an oral small molecule being investigated for the treatment of facioscapulohumeral muscular dystrophy (FSHD). Under the collaboration and license agreement, Sanofi obtains exclusive commercialization rights for losmapimod outside of the U.S.

The collaboration and license agreement combines Fulcrum's expertise in FSHD with Sanofi's global reach and unparalleled commitment to treating patients with rare diseases. Losmapimod is currently being evaluated in a global Phase 3 clinical trial for the treatment of FSHD, a chronic and progressive genetic muscular disorder that is characterized by significant muscle cell death and fat infiltration into muscle tissue. Results from ReDUX4, the Phase 2 clinical trial evaluating losmapimod for the treatment of FSHD, demonstrated a slowing of disease progression and improved muscle health. Fulcrum expects to report topline data from REACH, the global Phase 3 clinical trial, in the fourth quarter of 2024. Following positive data from the Phase 3 trial, Fulcrum and Sanofi plan to submit marketing applications in the U.S., Europe, Japan, and other geographies.

"Sanofi is a proven leader in developing therapeutics for rare neuromuscular diseases and is the ideal partner to maximize the opportunity and reach of losmapimod outside the U.S.," said Alex C. Sapir, Fulcrum's president and chief executive officer. "This deal aligns with our core strategy, allowing Fulcrum to remain focused on preparations for commercialization of losmapimod in the U.S., while leveraging Sanofi's exceptional global commercial capabilities and established infrastructure in key markets around the world. We are excited about the potential to provide the first approved treatment for FSHD patients, and we look forward to working with Sanofi to bring losmapimod to patients globally."

“This partnership provides an exciting opportunity to expand Sanofi’s rare disease franchise and deliver the first approved FSHD treatment to patients with the strength and reach of our commercial organization,” said Burcu Eryilmaz, Sanofi’s Global Head of Rare Diseases “Losmapimod has shown meaningful clinical benefits that underscore the disease-modifying potential and opportunity to address the high unmet need for a safe and effective drug that slows disease progression. With a deep commitment to bringing hope and new treatment options to patients, we look forward to working closely with Fulcrum as losmapimod advances through late-stage development.”

Per the terms of the agreement, Fulcrum will receive an upfront payment of $80.0 million and is eligible to receive up to an additional $975.0 million in specified regulatory and sales-based milestones, along with tiered escalating royalties starting in the low-teens on annual net sales of losmapimod outside the U.S. In addition, Fulcrum and Sanofi will equally share future global development costs.

Conference Call and Webcast
Individuals may register for the conference call by clicking the link here. Once registered, participants will receive dial-in details and unique PIN which will allow them to access the call. An audio webcast will be accessible through the Investor Relations section of the Fulcrum’s website at www.fulcrumtx.com or by clicking here. Following the live webcast, an archived replay will also be available.

About Losmapimod
Losmapimod is a selective p38α/β mitogen activated protein kinase (MAPK) inhibitor. Fulcrum exclusively in-licensed losmapimod from GSK following Fulcrum’s discovery of the role of p38α/β inhibitors in the reduction of DUX4 expression and an extensive review of known compounds. Results reported from the Phase 2 ReDUX4 trial demonstrated a slowing of disease progression and improved function, including positive impacts on upper extremity strength and functional measures supporting losmapimod’s potential to be a transformative therapy for the treatment of FSHD. Although losmapimod had never previously been explored in muscular dystrophies, it had been evaluated in more than 3,600 subjects in clinical trials across multiple other indications, with no safety signals attributed to losmapimod. Losmapimod has been granted U.S. Food and Drug Administration (FDA) Fast Track designation and Orphan Drug Designation for the treatment of FSHD. Losmapimod is currently being evaluated in a Phase 3 multi-center randomized, double-blind, placebo-controlled, 48-week parallel-group study in people with FSHD (NCT05397470).

About FSHD
FSHD is a serious, rare, progressive and debilitating disease for which there are no approved treatments. It is characterized by fat infiltration of skeletal muscle leading to muscular atrophy involving primarily the face, scapula and shoulders, upper arms, and abdomen. Impact on patients includes profound decreases in the ability to perform activities of daily living, loss of upper limb function, loss of mobility and independence and chronic pain. FSHD is one of the most common forms of muscular dystrophy and has an estimated patient population of 30,000 in the United States alone.

About Fulcrum Therapeutics
Fulcrum Therapeutics is a clinical-stage biopharmaceutical company focused on developing small molecules to improve the lives of patients with genetically defined rare diseases in areas of high unmet medical need. Fulcrum’s two lead programs in clinical development are losmapimod, a small molecule in development for the treatment of facioscapulohumeral muscular dystrophy (FSHD), and pociredir (formerly known as FTX-6058), a small molecule designed to increase expression of fetal hemoglobin and in development for the treatment of sickle cell disease (SCD). Fulcrum uses proprietary technology

to identify drug targets that can modulate gene expression to treat the known root cause of gene mis-expression. For more information, visit www.fulcrumtx.com and follow us on Twitter/X (@FulcrumTx) and LinkedIn.

Forward-Looking Statements
This press release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995 that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this press release are forward-looking statements, including express or implied statements regarding Fulcrum’s collaboration and license agreement with Sanofi and receipt of the upfront payment thereunder; its ability to receive the milestone and royalty payments thereunder and achieve benefits therefrom; timing of data from REACH and its ability to support submission of marketing applications for losmapimod; and Fulcrum’s ability to deliver an FDA-approved therapy for FSHD patients; among others. The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements are based on management’s current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in, or implied by, such forward-looking statements. These risks and uncertainties include, but are not limited to, risks associated with Fulcrum’s ability to continue to advance its product candidates in clinical trials; initiating and enrolling clinical trials on the timeline expected or at all; obtaining and maintaining necessary approvals from the FDA and other regulatory authorities; replicating in clinical trials positive results found in preclinical studies and/or earlier-stage clinical trials of losmapimod, pociredir and any other product candidates; obtaining, maintaining or protecting intellectual property rights related to its product candidates; managing expenses; managing executive and employee turnover, including integrating a new CMO; and raising the substantial additional capital needed to achieve its business objectives, among others. For a discussion of other risks and uncertainties, and other important factors, any of which could cause Fulcrum’s actual results to differ from those contained in the forward-looking statements, see the “Risk Factors” section, as well as discussions of potential risks, uncertainties, and other important factors, in Fulcrum’s most recent filings with the Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent Fulcrum’s views as of the date hereof and should not be relied upon as representing Fulcrum’s views as of any date subsequent to the date hereof. Fulcrum anticipates that subsequent events and developments will cause Fulcrum’s views to change. However, while Fulcrum may elect to update these forward-looking statements at some point in the future, Fulcrum specifically disclaims any obligation to do so.

Contact:
Chris Calabrese
LifeSci Advisors, LLC
ccalabrese@lifesciadvisors.com
917-680-5608

Schedule 14.8.1(a)
Baseball Arbitration Terms

[***]

Exhibit 10.2

THIRD AMENDMENT
TO
FULCRUM THERAPEUTICS, INC.
2022 INDUCEMENT STOCK INCENTIVE PLAN

A. The Fulcrum Therapeutics, Inc. 2022 Inducement Stock Incentive Plan, as amended (the "Plan") is hereby amended by deleting the first sentence of Section 4(a) and substituting therefore the following:

> "Subject to adjustment under Section 9, Awards may be made under the Plan for up to 6,150,000 shares of common stock, $0.001 par value per share, of the Company (the "***Common Stock***")."

B. The effective date of this Second Amendment shall be June 17, 2024.

C. Except as amended herein, the Plan is confirmed in all other respects.

Exhibit 10.3

CERTAIN INFORMATION CONTAINED IN THIS DOCUMENT, MARKED
BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE
TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL

AMENDMENT No. 2

This Amendment No. 2 (this **"Amendment No. 2"**) is effective as of the date signed by the last party to sign below (the "**Amendment No. 2 Effective Date"**) and is made and entered into by and among **Fulcrum Therapeutics, Inc., ("Fulcrum")** and **MyoKardia, Inc. ("MyoKardia")**.
Fulcrum and MyoKardia may each be referred to herein as a "**Party**" or collectively as the "**Parties**".

WHEREAS, Fulcrum and MyoKardia entered into a Collaboration and License Agreement having an effective date of July 20, 2020, as amended by Amendment 1, dated April 20, 2023 (collectively, the **"Agreement"**);

WHEREAS, Fulcrum and MyoKardia want to amend the Agreement to extend the term;

NOW, THEREFORE, in consideration of the foregoing premises and the mutual promises and covenants contained herein, Fulcrum and MyoKardia agree as follows:

1. The terms in this Amendment No. 2 with initial letters capitalized, whether used in the singular or the plural, shall have the meaning set forth herein, or if not defined herein, as set forth in the Agreement.

2. Section 1.60 is deleted in its entirety and replaced with the following:

"**Research Term**" means the period commencing on the Effective date and ending on [***].

3. Except as expressly set forth herein, all provisions of the Agreement shall remain unchanged and in full force and effect.

4. This Amendment No. 2 shall be governed by and interpreted in accordance with the substantive laws of the State of Delaware, without regard to conflict of law principles thereof.

5. This Amendment No. 2 may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one (1) and the same instrument. This Amendment No. 1 may be executed by facsimile or electronic (e.g., .pdf) signatures and such signatures shall be deemed to bind each party hereto as if they were original signatures.

IN WITNESS WHEREOF, the Parties have caused this Amendment No. 2 to be executed by their duly authorized representatives on the date(s) set forth below.

MYOKARDIA, INC.		**FULCRUM THERAPEUTICS, INC.**	
By:	/s/ Patrick Gliha	By:	/s/ Alex Sapir
Name:	Patrick Gliha	Name:	Alex Sapir
Title:	Executive Director, Global Alliances & Business Development	Title:	President and CEO
Date:	July 24, 2024	Date:	July 24, 2024

Exhibit 31.1

CERTIFICATION 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, Alex C. Sapir, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Fulcrum 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: July 31, 2024

By: /s/ Alex C. Sapir
Alex C. Sapir
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION 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, Alan Musso, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Fulcrum 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: July 31, 2024

By: /s/ Alan Musso
Alan Musso
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Fulcrum Therapeutics, Inc. (the "Company") for the period ended June 30, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Alex C. Sapir, President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

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

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

Date: July 31, 2024

By: /s/ Alex C. Sapir
Alex C. Sapir
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Fulcrum Therapeutics, Inc. (the "Company") for the period ended June 30, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Alan Musso, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

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

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

Date: July 31, 2024

By: /s/ Alan Musso
Alan Musso
Chief Financial Officer
(Principal Financial Officer)