# 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, 2020

OR

☐ TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE EXCHANGE ACT OF 1934

From the transition period from

to

Commission File Number 001-36076

## FATE THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

65-1311552 (IRS Employer Identification No.)

3535 General Atomics Court, Suite 200, San Diego, CA

(Address of principal executive offices)

92121 (Zip Code)

(858) 875-1800 (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	FATE	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 $\boxtimes$ No $\square$										
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 $\Box$								
Non-accelerated filer □ Emerging growth company □		Smaller reporting company $\Box$								
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. $\Box$										
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes $\square$ No $\boxtimes$										

As of August 3, 2020, 86,844,029 shares of the registrant's common stock, par value \$0.001 per share, were issued and outstanding.

## FATE THERAPEUTICS, INC.

## FORM 10-Q

## TABLE OF CONTENTS

		Page
<u>PART I. FINAN</u>	NCIAL INFORMATION	
Item 1.	Condensed Consolidated Financial Statements (unaudited)	3
	Condensed Consolidated Balance Sheets as of June 30, 2020 (unaudited) and December 31, 2019 (unaudited)	3
	Condensed Consolidated Statements of Operations and Comprehensive Loss for the three and six months ended June 30,	
	2020 and 2019 (unaudited)	2
	Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2020 and 2019 (unaudited)	
	Notes to Condensed Consolidated Financial Statements (unaudited)	(
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	21
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	31
Item 4.	Controls and Procedures	31
PART II. OTHE	ER INFORMATION	
Item 1.	<u>Legal Proceedings</u>	32
Item 1A.	Risk Factors	32
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	62
Item 3.	Defaults Upon Senior Securities	62
Item 4.	Mine Safety Disclosures	62
Item 5.	Other Information	62
Item 6.	<u>Exhibits</u>	63
<u>SIGNATURES</u>		64
	2	

## PART I. FINANCIAL INFORMATION

## Item 1. Condensed Consolidated Financial Statements (unaudited)

## Fate Therapeutics, Inc.

# Condensed Consolidated Balance Sheets (in thousands, except share and per share data)

Carrier assers:   Carrier asserts:   Carrier a			June 30, 2020	]	December 31, 2019	
Current inabilities         \$ 433,074         \$ 98,14           Accounts pecivable         1,717         —           Short-term investments and related maturity receivables         10,035         121,613           Prepaid expense and other current assets         5,099         5,652           Total current assets         540,225         227,089           Long-term investments         15,932         11,419           Operating lease right-of-use assets         68,229         22,752           Cellaboration contract assets         15,227         227           Collaboration contract assets         13,972         1,338           Other assets         9         9         9           Total assets         \$ 653,594         \$ 302,274           Labilities and Stockholders' Equity           Current liabilities           Accounts payable         \$ 13,563         \$ 5,822           Accounts payable         \$ 13,663         \$ 2,808           Operating lease liabilities, current portion         3,160         2,808           Operating lease liabilities, current portion         2,355         1,622           Operating lease liabilities, eur of current portion         7,802         2,780           Operating lease liabilities, net of curr	Access		(unau	dited)		
Cash and cash equivalents         \$ 433,074         \$ 99,814           Accounts receivable         1,177         —           Short-term investments and related maturity receivables         100,335         121,613           Prepaid expenses and other current assets         5,009         5,662           Cotal current assets         540,225         227,089           Long-term investments         —         39,440           Property and equipment, net         68,229         2,752           Quertiang lease right-of-use assets         68,229         2,752           Restricted cash         15,227         227           Collaboration contract assets         9         9         9           Other assets         9         9         9           Other assets         9         9         9           Collaboration contract assets         9         9         9           Other assets         9         9         9           Total assets         \$ 13,563         \$ 5,822           Accounts payable         \$ 13,563         \$ 5,822           Accrued expenses         11,618         14,697           CIRM award liability, current portion         2,355         1,592           Operating lease liab						
Accounts receivable         1,717         —           Short-term investments and related maturity receivables         100,335         126,163           Prepaid expenses and other current assets         5,009         5,602           Toal current assets         540,225         22,708           Droperty and equipment, net         15,932         11,419           Operating lease right-of-use assets         68,229         2,752           Restricted cash         13,972         13,38           Other assets         9         9           Total assets         5         63,594         30,274           Very Collaboration contract assets         1         13,972         1,338           Other assets         5         63,594         30,274           Total assets         5         63,594         30,274           Cates assets         5         63,594         30,274           Current Isabilities         11,618         14,602         2,780           Accounts payable         \$         13,618         1,802           Accounts payable         \$         13,618         1,802           Accounts payable         \$         1,502         2,780           CIRM award liability, current portion <t< td=""><td></td><td>¢</td><td>422.074</td><td>¢</td><td>00.014</td></t<>		¢	422.074	¢	00.014	
Short-term investments and related maturity receivables         100,335         121,613           Prepaid expenses and other current assets         50,09         5,662           Cholacturent assets         50,022         227,085           Long-term investments         15,932         11,419           Operating lease right-of-use assets         68,229         22,752           Restricted cash         13,227         227           Collaboration contract assets         13,227         1,338           Other assets         9         9           Total assets         5         653,394         302,274           Very Callaboration contract assets         19,09         1,09           Total assets         5         653,394         302,275           Value         5         653,594         302,275           Value         5         653,594         302,275           Value         5         15,262         302,275           Accounts payable         \$         13,69         2,802           Accounts payable         \$         11,618         14,697           CIRM award liability, current portion         3,169         2,275           Operating lease liabilities, eurent portion         7,863         3,2	-	Ф		Ф	99,014	
Prepaid expenses and other current assets         5,009         5,602           Total current assets         540,225         227,008           Long-termit revisements         15,932         11,119           Operating lease right-of-use assets         68,229         22,752           Restricted cash         15,227         227           Collaboration contract assets         13,072         1,338           Other assets         9         9         9           Total assets         \$653,594         \$0,202,70           Total assets         \$13,503         \$0,202,70           Total current liabilities         \$13,503         \$0,202,70           CIRM award liability, current portion         \$1,602         \$2,780           Operating lease liabilities, current portion         \$2,503         \$1,602           CIRM award liability, euter of current portion         \$5,608         \$3,755           CIRM award liability, euter of current porti			,		121 613	
Total current assets         540,225         227,089           Long-term investments         —         39,440           Property and equipment, net         615,232         11,419           Operating lease right-of-use assets         68,229         22,752           Restricted cash         15,227         227           Collaboration contract assets         9         9         9           Otal assets         9         9         9           Total assets         9         9         9           Total assets         9         9         9           Count assets         9         9         9         9           Count assets         9         3         30,222         3         3         3         2         2         2         2         3         3         3         2         2         2         4         2         2         8         3         3         3         2         2         2         3	· ·		,			
Long-term investments         39,440           Property and equipment, net         15,932         11,419           Operating lease right-of-use assets         68,229         22,75           Restricted cash         15,227         227           Collaboration contract assets         13,972         1,338           Other assets         9         9           Total assets         \$635,394         \$02,274           Labilities and Stockholders' Equity           Use the Hilbert In Italian In Italian In Italian						
Property and equipment, net         15,932         11,419           Operating lease right-of-use assets         68,29         22,752           Restricted cash         15,227         227           Collaboration contract assets         13,972         1,338           Other assets         9         9           Total assets         653,594         \$ 302,274           Labilities and Stockholders' Equity           Userent liabilities           Current liabilities         \$ 13,563         \$ 5,822           Accounts payable         \$ 13,563         \$ 5,822           Accounts payable         \$ 13,663         \$ 14,692           CIRM award liability, current portion         3,160         2,808           Deferred revenue, current portion         45,322         27,806           Operating lease liabilities, current portion         5,468         3,775           CIRM award liability, net of current portion         76,63         2,235           Cleffered evenue, net of current portion         76,63         2,235           Cleffered sevenue, net of current portion         76,63         2,235           Cleffered sevenue, net of current portion         76,63         2,235           Clemmitternia back convertible research services         <			540,225			
Operating lease right-of-use assets         68,229         22,752           Restricted cash         15,227         227           Collaboration contract assets         13,972         1,338           Other assets         9         9           Total assets         \$653,594         \$302,274           Liabilities and Stockholders' Equity           Ure restribubilities           Accounts payable         \$13,563         \$5,822           Accounted expenses         11,618         14,697           CIRM award liability, current portion         3,160         2,808           Deferred revenue, current portion         3,160         2,808           Deferred revenue, current portion         45,322         27,806           Deferred revenue, ent of current portion         54,688         3,775           CIRM award liability, net of current portion         78,683         3,755           Deferred revenue, tent of current portion         78,683         3,755           CIRM award liability, net of current portion         78,683         3,755           CIRM award liability, net of current portion         78,683         3,755           CIRM award liability, net of current portion         78,683         3,755           Commitm	5		15.022			
Restricted cash         15,227         227           Collaboration contract assets         13,972         1,338           Other assets         9         9           Total assets         \$635,394         \$302,274           Lisibilities and Stockholders' Equity           Current liabilities           Accounts payable         \$13,563         \$5,822           Accounts payable         \$13,663         \$6,822           CIRM award liability, current portion         3,160         2,808           Deferred revenue, current portion         14,626         2,787           Opea ting lease liabilities, current portion         45,322         27,806           Total current liabilities         45,322         27,806           Deferred revenue, net of current portion         76,863         3,752           CIRM award liability, net of current portion         76,863         3,752           Cill quarrent portion         76,863         3,752           Commitments and contingencies         8         3,752           Commitments and contingencies         8         3,752           Preferred stock, \$0,001 par value; authorized shares—5,000,000         3         3         3           ar June 30, 2020 and December 31, 2019; Class A Co	1 5 1 1				*	
Collaboration contract assets         13,972         1,388           Other assets         9         9           Total assets         6 563,594         3 02,274           Listbilities and Stockholders' Equity           Users           Accounts payable         S 15,653         5.822           Accounts payable         11,618         14,626         2,088           CIRM award liability, current portion         14,626         2,787         1,626         2,088         1,626         2,787         1,626         2,780						
Other assets         9         9           Total assets         6 563,594         3 030,274           Labilities and Stockholders' Equity           Current liabilities           Accounts payable         \$ 13,563         5,822           Accounts payable         \$ 13,563         5,822           CIRM award liability, current portion         3,160         2,808           Deferred revenue, current portion         14,626         2,787           Operating lease liabilities, current portion         45,222         27,806           Cital current liabilities         45,222         27,806           Deferred revenue, net of current portion         54,688         3,775           CIRM award liability, net of current portion         70         70           Operating lease liabilities, net of current portion         70         70           Commitments and contingencies         3         75           Stockholders' equity:         3         2,535         1,502           Preferred stock, \$0,001 par value; authorized shares—5,000,000         3         3         3         3         3           Common stock, \$0,001 par value; authorized shares—150,000,000         3         3         3         3         3           Line 30, 2020						
Total assets         \$ 653,594         \$ 302,274           Liabilities and Stockholders' Equity           Current liabilities:           Accounts payable         \$ 13,563         \$ 5,822           Accued expenses         11,618         14,697           CIRM award liability, current portion         3,160         2,808           Deferred revenue, current portion         14,626         2,787           Operating lease liabilities, current portion         45,322         27,806           Deferred revenue, net of current portion         45,322         27,806           Deferred revenue, net of current portion         790         702           CIRM award liability, net of current portion         790         702           Operating lease liabilities, net of current portion         790         702           Operating lease liabilities, net of current portion         790         702           Operating lease liabilities, net of current portion         790         702           Operating lease liabilities, net of current portion         790         702           Operating lease liabilities, net of current portion         790         702           Committents and contingencies           Preferred stock, \$0.001 par value; authorized shares—5,000,000         3						
Current liabilities and Stockholders' Equity   Surprise   Surpri		<del> </del>				
Current liabilities:         \$ 13,563         \$ 5,822           Accounts payable         \$ 13,563         \$ 5,822           Accrued expenses         11,618         2,808           CIRM award liability, current portion         3,160         2,808           Deferred revenue, current portion         2,355         1,692           Total current liabilities         45,322         27,806           Deferred revenue, net of current portion         54,688         3,775           Deferred revenue, net of current portion         78,683         25,235           CIRM award liability, net of current portion         78,683         25,235           Commitments and contingencies         78,683         25,235           Commitments and contingencies         78,683         25,235           Preferred stock, \$0.001 par value; authorized shares—5,000,000         3         3         3           Oscabilities, euron portion         3         3         3         3           Preferred stock, \$0.001 par value; authorized shares—5,000,000         3         3         3         3         3           Preferred stock, \$0.001 par value; authorized shares—150,000,000 at         3         3         3         3         3         3         3         3         3         3	Total assets	\$	653,594	\$	302,274	
Current liabilities:         \$ 13,563         \$ 5,822           Accounts payable         \$ 13,563         \$ 5,822           Accrued expenses         11,618         2,808           CIRM award liability, current portion         3,160         2,808           Deferred revenue, current portion         2,355         1,692           Total current liabilities         45,322         27,806           Deferred revenue, net of current portion         54,688         3,775           Deferred revenue, net of current portion         78,683         25,235           CIRM award liability, net of current portion         78,683         25,235           Commitments and contingencies         78,683         25,235           Commitments and contingencies         78,683         25,235           Preferred stock, \$0.001 par value; authorized shares—5,000,000         3         3         3           Oscabilities, euron portion         3         3         3         3           Preferred stock, \$0.001 par value; authorized shares—5,000,000         3         3         3         3         3           Preferred stock, \$0.001 par value; authorized shares—150,000,000 at         3         3         3         3         3         3         3         3         3         3						
Accounts payable         \$ 13,563         \$ 5,822           Accrued expenses         11,618         14,697           CIRM award liability, current portion         3,160         2,808           Deferred revenue, current portion         14,626         2,787           Operating lease liabilities, current portion         45,322         27,806           Deferred revenue, net of current portion         54,688         3,775           CIRM award liability, net of current portion         790         702           Operating lease liabilities, net of current portion         78,683         25,235           Commitments and contringencies         786,883         25,235           Stockholders' equity         87         76           Preferred stock, \$0,001 par value; authorized shares—5,000,000         3         3         3           at June 30, 2020 and December 31, 2019; Class A Convertible Preferred shares issued and outstanding—2,794,549 at June 30, 2020 and December 31, 2019         3         3         3           Common stock, \$0,001 par value; authorized shares—150,000,000 at June 30, 2020 and December 31, 2019; issued and outstanding—86,802,162         48         76           Additional paid-in capital         918,535         628,200           Accumulated other comprehensive gain         623         22           Accumulated other c	Liabilities and Stockholders' Equity					
Accrued expenses         11,618         14,697           CIRM award liability, current portion         3,160         2,808           Deferred revenue, current portion         14,626         2,787           Operating lease liabilities, current portion         2,355         1,692           Total current liabilities         45,322         27,806           Deferred revenue, net of current portion         54,688         3,775           CIRM award liability, net of current portion         790         702           Operating lease liabilities, net of current portion         78,683         25,235           Commitments and contingencies         5         5           Stockholders' equity:         8         7           Preferred stock, \$0.001 par value; authorized shares—5,000,000         3         3           at June 30, 2020 and December 31, 2019; Class A Convertible Preferred shares issued and outstanding—2,794,549 at June 30, 2020 and December 31, 2019; at June 30, 2020 and December 31, 2019; sisued and outstanding—86,802,162         3         3           at June 30, 2020 and December 31, 2019; issued and outstanding—86,802,162         87         62,200           Additional paid-in capital         918,535         628,200           Accumulated other comprehensive gain         623         22           Accumulated deficit         (445,137) <td>Current liabilities:</td> <td></td> <td></td> <td></td> <td></td>	Current liabilities:					
CIRM award liability, current portion         3,160         2,808           Deferred revenue, current portion         14,626         2,787           Operating lease liabilities, current portion         2,355         1,692           Total current liabilities         45,322         27,806           Deferred revenue, net of current portion         54,688         3,775           CIRM award liability, net of current portion         790         702           Operating lease liabilities, net of current portion         78,683         25,235           Commitments and contingencies         8         25,235           Commitments and contingencies         8         8           Stockholders' equity:         8         8         25,235           Preferred stock, \$0,001 par value; authorized shares—5,000,000         8         8         25,235           Commitments and contingencies         8         3         3         3           Tockholders' equity:         8         3 <t< td=""><td>Accounts payable</td><td>\$</td><td>13,563</td><td>\$</td><td>5,822</td></t<>	Accounts payable	\$	13,563	\$	5,822	
Deferred revenue, current portion         14,626         2,787           Operating lease liabilities, current portion         2,355         1,692           Total current liabilities         45,322         27,806           Deferred revenue, net of current portion         54,688         3,775           CIRM award liability, net of current portion         790         702           Operating lease liabilities, net of current portion         78,683         25,235           Commitments and contingencies         5         5           Stockholders' equity:         7         7           Preferred stock, \$0,001 par value; authorized shares—5,000,000         3         3           at June 30, 2020 and December 31, 2019; Class A Convertible Preferred shares issued and outstanding—2,794,549 at June 30, 2020 and December 31, 2019         3         3           Common stock, \$0,001 par value; authorized shares—150,000,000 at June 30, 2020 and December 31, 2019; issued and outstanding—86,802,162         87         76           Additional paid-in capital         918,535         628,200           Accumulated other comprehensive gain         623         22           Accumulated deficit         (445,137)         (383,545)           Total stockholders' equity         474,111         244,756	Accrued expenses		11,618		14,697	
Operating lease liabilities, current portion         2,355         1,692           Total current liabilities         45,322         27,806           Deferred revenue, net of current portion         54,688         3,775           CIRM award liability, net of current portion         790         702           Operating lease liabilities, net of current portion         78,683         25,235           Commitments and contingencies         ************************************	CIRM award liability, current portion		3,160		2,808	
Total current liabilities         45,322         27,806           Deferred revenue, net of current portion         54,688         3,775           CIRM award liability, net of current portion         790         702           Operating lease liabilities, net of current portion         78,683         25,235           Commitments and contingencies         ************************************	Deferred revenue, current portion		14,626		2,787	
Deferred revenue, net of current portion         54,688         3,775           CIRM award liability, net of current portion         790         702           Operating lease liabilities, net of current portion         78,683         25,235           Commitments and contingencies         ****         ****           Stockholders' equity:         ****         ****           Preferred stock, \$0.001 par value; authorized shares—5,000,000         ****         ****           at June 30, 2020 and December 31, 2019; Class A Convertible Preferred shares issued and outstanding—2,794,549 at June 30, 2020 and December 31, 2019         3         3           Common stock, \$0.001 par value; authorized shares—150,000,000 at June 30, 2020 and December 31, 2019; issued and outstanding—86,802,162         ***         ***           at June 30, 2020 and 75,730,260 at December 31, 2019         87         76           Additional paid-in capital         918,535         628,200           Accumulated other comprehensive gain         623         22           Accumulated deficit         (445,137)         (383,545)           Total stockholders' equity         474,111         244,756	Operating lease liabilities, current portion		2,355		1,692	
CIRM award liability, net of current portion       790       702         Operating lease liabilities, net of current portion       78,683       25,235         Commitments and contingencies       Stockholders' equity:         Preferred stock, \$0.001 par value; authorized shares—5,000,000 at June 30, 2020 and December 31, 2019; Class A Convertible Preferred shares issued and outstanding—2,794,549 at June 30, 2020 and December 31, 2019       3       3         Common stock, \$0.001 par value; authorized shares—150,000,000 at June 30, 2020 and December 31, 2019; issued and outstanding—86,802,162 at June 30, 2020 and 75,730,260 at December 31, 2019       87       76         Additional paid-in capital       918,535       628,200         Accumulated other comprehensive gain       623       22         Accumulated deficit       (445,137)       (383,545)         Total stockholders' equity       474,111       244,756	Total current liabilities		45,322		27,806	
CIRM award liability, net of current portion       790       702         Operating lease liabilities, net of current portion       78,683       25,235         Commitments and contingencies       Stockholders' equity:         Preferred stock, \$0.001 par value; authorized shares—5,000,000 at June 30, 2020 and December 31, 2019; Class A Convertible Preferred shares issued and outstanding—2,794,549 at June 30, 2020 and December 31, 2019       3       3         Common stock, \$0.001 par value; authorized shares—150,000,000 at June 30, 2020 and December 31, 2019; issued and outstanding—86,802,162 at June 30, 2020 and 75,730,260 at December 31, 2019       87       76         Additional paid-in capital       918,535       628,200         Accumulated other comprehensive gain       623       22         Accumulated deficit       (445,137)       (383,545)         Total stockholders' equity       474,111       244,756	Deferred revenue, net of current portion		54,688		3,775	
Operating lease liabilities, net of current portion       78,683       25,235         Commitments and contingencies       Stockholders' equity:         Preferred stock, \$0.001 par value; authorized shares—5,000,000 at June 30, 2020 and December 31, 2019; Class A Convertible Preferred shares issued and outstanding—2,794,549 at June 30, 2020 and December 31, 2019       3       3         Common stock, \$0.001 par value; authorized shares—150,000,000 at June 30, 2020 and December 31, 2019; issued and outstanding—86,802,162 at June 30, 2020 and 75,730,260 at December 31, 2019       87       76         Additional paid-in capital       918,535       628,200         Accumulated other comprehensive gain       623       22         Accumulated deficit       (445,137)       (383,545)         Total stockholders' equity       474,111       244,756			790		702	
Stockholders' equity:       Preferred stock, \$0.001 par value; authorized shares—5,000,000 at June 30, 2020 and December 31, 2019; Class A Convertible Preferred shares issued and outstanding—2,794,549 at June 30, 2020 and December 31, 2019       3       3         Common stock, \$0.001 par value; authorized shares—150,000,000 at June 30, 2020 and December 31, 2019; issued and outstanding—86,802,162 at June 30, 2020 and 75,730,260 at December 31, 2019       87       76         Additional paid-in capital       918,535       628,200         Accumulated other comprehensive gain       623       22         Accumulated deficit       (445,137)       (383,545)         Total stockholders' equity       474,111       244,756			78,683		25,235	
Stockholders' equity:       Preferred stock, \$0.001 par value; authorized shares—5,000,000 at June 30, 2020 and December 31, 2019; Class A Convertible Preferred shares issued and outstanding—2,794,549 at June 30, 2020 and December 31, 2019       3       3         Common stock, \$0.001 par value; authorized shares—150,000,000 at June 30, 2020 and December 31, 2019; issued and outstanding—86,802,162 at June 30, 2020 and 75,730,260 at December 31, 2019       87       76         Additional paid-in capital       918,535       628,200         Accumulated other comprehensive gain       623       22         Accumulated deficit       (445,137)       (383,545)         Total stockholders' equity       474,111       244,756	Commitments and contingencies					
at June 30, 2020 and December 31, 2019; Class A Convertible Preferred       shares issued and outstanding—2,794,549 at June 30, 2020 and December 31, 2019       3       3         Common stock, \$0.001 par value; authorized shares—150,000,000 at June 30, 2020 and December 31, 2019; issued and outstanding—86,802,162 at June 30, 2020 and 75,730,260 at December 31, 2019       87       76         Additional paid-in capital       918,535       628,200         Accumulated other comprehensive gain       623       22         Accumulated deficit       (445,137)       (383,545)         Total stockholders' equity       474,111       244,756	Stockholders' equity:					
Common stock, \$0.001 par value; authorized shares—150,000,000 at June 30, 2020 and December 31, 2019; issued and outstanding—86,802,162 at June 30, 2020 and 75,730,260 at December 31, 2019       87       76         Additional paid-in capital       918,535       628,200         Accumulated other comprehensive gain       623       22         Accumulated deficit       (445,137)       (383,545)         Total stockholders' equity       474,111       244,756	at June 30, 2020 and December 31, 2019; Class A Convertible Preferred shares issued and outstanding—2,794,549 at June 30, 2020 and					
June 30, 2020 and December 31, 2019; issued and outstanding—86,802,162       87       76         at June 30, 2020 and 75,730,260 at December 31, 2019       87       76         Additional paid-in capital       918,535       628,200         Accumulated other comprehensive gain       623       22         Accumulated deficit       (445,137)       (383,545)         Total stockholders' equity       474,111       244,756			3		3	
Additional paid-in capital       918,535       628,200         Accumulated other comprehensive gain       623       22         Accumulated deficit       (445,137)       (383,545)         Total stockholders' equity       474,111       244,756	June 30, 2020 and December 31, 2019; issued and outstanding—86,802,162		87		76	
Accumulated other comprehensive gain62322Accumulated deficit(445,137)(383,545)Total stockholders' equity474,111244,756			918,535		628,200	
Accumulated deficit         (445,137)         (383,545)           Total stockholders' equity         474,111         244,756			623		22	
Total stockholders' equity 474,111 244,756			(445,137)		(383,545)	
	Total stockholders' equity					
		\$		\$		

See accompanying notes.

## Fate Therapeutics, Inc.

# Condensed Consolidated Statements of Operations and Comprehensive Loss (in thousands, except share and per share data)

	Three Months Ended June 30,			Six Months Ended Ju			June 30,	
		2020		2019		2020		2019
		(unau				•	audited)	
Collaboration revenue	\$	5,465	\$	2,817	\$	7,980	\$	5,449
Operating expenses:								
Research and development		26,669		21,631		55,947		39,359
General and administrative		7,503		5,270		15,232		10,620
Total operating expenses		34,172		26,901		71,179		49,979
Loss from operations		(28,707)		(24,084)		(63,199)		(44,530)
Other income (expense):								
Interest income		635		1,015		1,607		2,106
Interest expense		_		(409)		<u> </u>		(814)
Total other income, net		635		606		1,607		1,292
Net loss	\$	(28,072)	\$	(23,478)	\$	(61,592)	\$	(43,238)
Other comprehensive income (loss):								
Unrealized gain on available-for-sale securities, net		481		93		601		95
Comprehensive loss	\$	(27,591)	\$	(23,385)	\$	(60,991)	\$	(43,143)
Net loss per common share, basic and diluted	\$	(0.35)	\$	(0.36)	\$	(0.79)	\$	(0.66)
Weighted-average common shares used to compute basic and diluted net								
loss per share		79,304,627	_	65,213,364	_	77,595,795	_	65,067,801

See accompanying notes.

## Fate Therapeutics, Inc.

# Condensed Consolidated Statements of Cash Flows (in thousands)

		Six Months Ended June 30,			
		2020	P. D	2019	
Operating activities		(unau	dited)		
Net loss	\$	(61,592)	\$	(43,238)	
Adjustments to reconcile net loss to net cash used in operating activities:	Ψ	(01,552)	Ψ	(15,250)	
Depreciation and amortization		1,453		983	
Stock-based compensation		14,149		8,254	
Amortization of debt discounts and debt issuance costs				32	
Accretion and amortization of premiums and discounts on investments, net		518		(303)	
Amortization of collaboration contract assets		644		271	
Noncash interest expense		_		159	
Deferred revenue		62,753		(4,795)	
Changes in operating assets and liabilities:		, , , , ,		( , == ,	
Accounts receivable		(1,717)		500	
Prepaid expenses and other assets		(12,788)		519	
Accounts payable and accrued expenses		4,804		(893	
Right-of-use assets and lease liabilities, net		3,944		709	
Net cash provided by (used in) operating activities		12,168		(37,802	
Investing activities				(01,000	
Purchases of property and equipment		(1,706)		(3,541	
Purchases of investments		_		(106,182	
Maturities of investments		60,800		26,500	
Net cash provided by (used in) investing activities		59,094		(83,223	
Financing activities		,		(,	
Issuance of common stock from equity incentive plans, net of issuance costs		3,570		1,946	
Proceeds from public offering of common stock, net of issuance costs		189,054		_	
Proceeds from private placement of common stock, net of issuance costs		50,000		_	
Proceeds from sale of common stock to collaboration partner, net of issuance costs		33,934		_	
Proceeds from CIRM award		440		_	
Net cash provided by financing activities		276,998	-	1,946	
Net change in cash, cash equivalents and restricted cash		348,260		(119,079	
Cash, cash equivalents and restricted cash at beginning of the period		100,041		190,741	
Cash, cash equivalents and restricted cash at end of the period	\$	448,301	\$	71,662	
Supplemental disclosure of cash flow information	<u>*</u>		- <del></del>	,,	
Interest paid	\$		\$	626	
Supplemental schedule of noncash investing and financing activities	Ψ	<del></del>	Ψ	020	
Purchases of property and equipment in accounts payable	\$	172	\$	1,053	
Right-of use assets obtained in exchange for lease obligations	\$	48,226	\$	7,705	
ragin-or use assets obtained in exchange for rease obligations	Ψ	40,220	Ψ	7,703	

See accompanying notes.

### Fate Therapeutics, Inc.

# Notes to Condensed Consolidated Financial Statements (Unaudited)

#### 1. Organization and Summary of Significant Accounting Policies

#### Organization

Fate Therapeutics, Inc. (the Company) was incorporated in the state of Delaware on April 27, 2007 and has its principal operations in San Diego, California. The Company is a clinical-stage biopharmaceutical company dedicated to the development of programmed cellular immunotherapies for cancer and immune disorders. The Company's therapeutic pipeline is comprised of immuno-oncology programs, including off-the-shelf engineered natural killer (NK) and T-cell product candidates derived from clonal master induced pluripotent stem cell (iPSC) lines, and immuno-regulatory programs, including product candidates to prevent life-threatening complications in patients undergoing hematopoietic cell transplantation. The Company's product candidates are based on its proprietary cell programming approach, which it applies to modulate the therapeutic function and direct the fate of immune cells.

As of June 30, 2020, the Company has devoted substantially all of its efforts to product development, raising capital and building infrastructure and has not generated any revenues from any sales of its therapeutic products. To date, the Company's revenues have been derived from collaboration agreements and government grants.

#### **Public Equity Offerings**

In June 2020, the Company completed a public offering of common stock in which investors, certain of which are affiliated with a director of the Company, purchased 7.1 million shares of the Company's common stock at a price of \$28.31 per share under a shelf registration statement. Gross proceeds from the offering were \$201.3 million, and, after giving effect to \$12.5 million of costs related to the offering (of which \$0.3 million was unpaid as of June 30, 2020), net proceeds were \$188.8 million.

In September 2019, the Company completed a public offering of common stock in which investors, certain of which are affiliated with a director of the Company, purchased 9.9 million shares of the Company's common stock at a price of \$17.50 per share under a shelf registration statement. Gross proceeds from the offering were \$173.1 million, and, after giving effect to \$10.7 million of costs related to the offering, net proceeds were \$162.4 million.

#### **Private Placements of Common Stock**

In June 2020, in connection with the June 2020 public offering of common stock, the Company exercised its right to cause an existing shareholder, Johnson & Johnson Innovation-JJDC, Inc (JJDC), to purchase \$50.0 million of the Company's common stock, and JJDC purchased in a private placement 1.8 million shares of the Company's common stock at a price of \$28.31 per share, for aggregate proceeds of \$50.0 million. In April 2020, in connection with the Janssen Agreement described in Note 2, JJDC purchased in a private placement 1.6 million shares of the Company's common stock at a price of \$31.00 per share, for aggregate proceeds of \$50.0 million. The shares of common stock purchased in the private placements were not subject to any underwriting discounts or commissions.

#### **Use of Estimates**

The Company's unaudited condensed consolidated financial statements are prepared in accordance with United States generally accepted accounting principles (U.S. GAAP). The preparation of the Company's unaudited condensed consolidated financial statements requires management to make estimates and assumptions that impact the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in the Company's unaudited condensed consolidated financial statements and accompanying notes. The most significant estimates and assumptions in the Company's unaudited condensed consolidated financial statements relate to its contracts containing leases, accrued expenses and the estimated total costs expected to be incurred under the Company's collaboration agreements. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

#### **Risks and Uncertainties**

Due to the global outbreak of SARS-CoV-2, the novel strain of coronavirus that causes Coronavirus disease 19 (COVID-19), the Company experienced impacts on certain aspects of its business, including its clinical trial and research and development activities, during the six months ended June 30, 2020. For example, certain of the Company's research and development activities have been delayed or disrupted as a result of measures the Company implemented in response to governmental "stay at home" orders and in the interests of public health and safety, and the Company has experienced delays or disruptions in the initiation and conduct of its clinical trials as a result of prioritization of hospital and other medical resources toward pandemic efforts, policies and procedures implemented at clinical sites with respect to the conduct of clinical trials, and other precautionary measures taken in treating patients or in practicing medicine in response to the COVID-19 pandemic. The scope and duration of these delays and disruptions, and the ultimate impacts of COVID-19 on the Company's operations, are currently unknown. The Company is continuing to actively monitor the situation and may take further precautionary and preemptive actions as may be required by federal, state or local authorities or that it determines are in the best interests of public health and safety and that of the Company's patient community, employees, partners, and stockholders. The Company cannot predict the effects that such actions, or the impact of COVID-19 on global business operations and economic conditions, may have on its business, strategy, collaborations, or financial and operating results.

#### **Principles of Consolidation**

The unaudited condensed consolidated financial statements include the accounts of the Company and its subsidiaries, Fate Therapeutics Ltd., incorporated in the United Kingdom, Fate Therapeutics, B.V., incorporated in the Netherlands and Tfinity Therapeutics, Inc., incorporated in the United States. To date, the aggregate operations of these subsidiaries have not been significant and all intercompany transactions and balances have been eliminated in consolidation.

#### Cash, Cash Equivalents and Restricted Cash

Cash and cash equivalents include cash in readily available checking and savings accounts, money market accounts and money market funds. The Company considers all highly liquid investments with an original maturity of three months or less from the date of purchase to be cash equivalents.

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the unaudited condensed consolidated balance sheets that sum to the total of the same such amount shown in the unaudited condensed consolidated statements of cash flows as of June 30, 2020 and 2019 (in thousands):

	 Six Months Ended June 30,				
	 2020		2019		
Cash and cash equivalents	\$ 433,074	\$	71,435		
Restricted cash	15,227		227		
Total cash, cash equivalents, and restricted cash shown in the unaudited	 				
condensed consolidated statement of cash flows	\$ 448,301	\$	71,662		

During the six months ended June 30, 2020, the Company entered into a lease for a facility in San Diego that it intends to use as its new corporate headquarters. In lieu of a security deposit, Silicon Valley Bank issued a \$15.0 million letter of credit on the Company's behalf, which letter of credit is secured by a deposit of equal amount. For the six months ended June 30, 2020 and 2019, the restricted cash balance includes cash-collateralized irrevocable standby letters of credit in the amounts of \$15.2 million and \$0.2 million, respectively, associated with the Company's facilities leases.

#### **Investments**

Investments are accounted for as available-for-sale securities and are carried at fair value on the unaudited condensed consolidated balance sheets. Upon initial recognition of the investment and at each reporting period, the Company evaluates whether any unrealized losses on investments are attributable to a credit loss or other factors. Any unrealized losses attributable to credit loss are recorded through an allowance for credit losses, limited to the amount by which the fair value is below amortized cost, with the offsetting amount recorded in other income or expense in the unaudited condensed consolidated statement of operations and comprehensive loss. Unrealized losses not attributable to an expected credit loss and unrealized gains on investments are recorded in other comprehensive income (loss) on the condensed consolidated statements of operations and comprehensive loss. Realized gains and losses, if any, on investments classified as available-for-sale securities are included in other income or expense.

The amortized cost of investments classified as available-for-sale debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion are included in interest income. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in interest income.

#### **Unaudited Interim Financial Information**

The accompanying interim condensed consolidated financial statements are unaudited. These unaudited interim condensed consolidated financial statements have been prepared in accordance with U.S. GAAP and following the requirements of the United States Securities and Exchange Commission (SEC) for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required can be condensed or omitted. The interim unaudited condensed consolidated financial statements should be read in conjunction with the Company's financial statements and accompanying notes for the fiscal year ended December 31, 2019, contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2019 filed by the Company with the SEC on March 2, 2020. In management's opinion, the unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited financial statements and include all adjustments, which include only normal recurring adjustments, necessary for the fair presentation of the Company's financial position and its results of operations and comprehensive loss and its cash flows for the periods presented. The results for the three and six months ended June 30, 2020 are not necessarily indicative of the results expected for the full fiscal year or any other interim period or any future year or period.

#### **Revenue Recognition**

The Company recognizes revenue in a manner that depicts the transfer of control of a product or a service to a customer and reflects the amount of the consideration the Company is entitled to receive in exchange for such product or service. In doing so, the Company follows a five-step approach: (i) identify the contract with a customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations, and (v) recognize revenue when (or as) the customer obtains control of the product or service. The Company considers the terms of a contract and all relevant facts and circumstances when applying the revenue recognition standard. The Company applies the revenue recognition standard, including the use of any practical expedients, consistently to contracts with similar characteristics and in similar circumstances.

A customer is a party that has entered into a contract with the Company, where the purpose of the contract is to obtain a product or a service that is an output of the Company's ordinary activities in exchange for consideration. To be considered a contract, (i) the contract must be approved (in writing, orally, or in accordance with other customary business practices), (ii) each party's rights regarding the product or the service to be transferred can be identified, (iv) the contract must have commercial substance (that is, the risk, timing or amount of future cash flows is expected to change as a result of the contract), and (v) it is probable that the Company will collect substantially all of the consideration to which it is entitled to receive in exchange for the transfer of the product or the service.

A performance obligation is defined as a promise to transfer a product or a service to a customer. The Company identifies each promise to transfer a product or a service (or a bundle of products or services, or a series of products and services that are substantially the same and have the same pattern of transfer) that is distinct. A product or a service is distinct if both (i) the customer can benefit from the product or the service either on its own or together with other resources that are readily available to the customer and (ii) the Company's promise to transfer the product or the service to the customer is separately identifiable from other promises in the contract. Each distinct promise to transfer a product or a service is a unit of accounting for revenue recognition. If a promise to transfer a product or a service is not separately identifiable from other promises in the contract, such promises should be combined into a single performance obligation.

The transaction price is the amount of consideration the Company is entitled to receive in exchange for the transfer of control of a product or a service to a customer. To determine the transaction price, the Company considers the existence of any significant financing component, the effects of any variable elements, noncash considerations and consideration payable to the customer. If a significant financing component exists, the transaction price is adjusted for the time value of money. If an element of variability exists, the Company must estimate the consideration it expects to receive and uses that amount as the basis for recognizing revenue as the product or the service is transferred to the customer. There are two methods for determining the amount of variable consideration: (i) the expected value method, which is the sum of probability-weighted amounts in a range of possible consideration amounts, and (ii) the mostly likely amount method, which identifies the single most likely amount in a range of possible consideration amounts.

If a contract has multiple performance obligations, the Company allocates the transaction price to each distinct performance obligation in an amount that reflects the consideration the Company is entitled to receive in exchange for satisfying each distinct performance obligation. For each distinct performance obligation, revenue is recognized when (or as) the Company transfers control of the product or the service applicable to such performance obligation.

In those instances where the Company first receives consideration in advance of satisfying its performance obligation, the Company classifies such consideration as deferred revenue until (or as) the Company satisfies such performance obligation. In those instances where the Company first satisfies its performance obligation prior to its receipt of consideration, the consideration is recorded as accounts receivable.

The Company expenses incremental costs of obtaining and fulfilling a contract as and when incurred if the expected amortization period of the asset that would be recognized is one year or less, or if the amount of the asset is immaterial. Otherwise, such costs are capitalized as contract assets if they are incremental to the contract and amortized to expense proportionate to revenue recognition of the underlying contract.

#### Leases

The Company determines if a contract contains a lease at the inception of the contract. The Company currently has leases related to its facilities leased for office and laboratory space, which are classified as operating leases. These leases result in operating right-of-use (ROU) assets, current operating lease liabilities, and non-current operating lease liabilities in the unaudited condensed consolidated balance sheets. The Company does not have any financing leases. Leases with a term of 12 months or less are considered short-term and a ROU asset and lease obligation are not recognized. Payments associated with short-term leases are expensed on a straight-line basis over the lease term.

Lease liabilities represent an obligation to make lease payments arising from the lease and ROU assets represent the right to use the underlying asset identified in the lease for the lease term. Lease liabilities are measured at the present value of the lease payments not yet paid discounted using the discount rate for the lease established at the lease commencement date. To determine the present value, the implicit rate is used when readily determinable. For those leases where the implicit rate is not provided, the Company determines an incremental borrowing rate based on the information available at the lease commencement date in determining the present value of lease payments. ROU assets are measured as the present value of the lease payments and also include any prepaid lease payments made and any other indirect costs incurred, and exclude any lease incentives received. Lease terms may include the impact of options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Lease expense for operating leases is recognized on a straight-line basis over the lease term. The Company aggregates all lease and non-lease components for each class of underlying assets into a single lease component.

#### **Stock-Based Compensation**

Stock-based compensation expense represents the cost of the grant date fair value of employee stock option and restricted stock unit grants recognized over the requisite service period of the awards (usually the vesting period) on a straight-line basis. For stock option grants for which vesting is subject to performance-based milestones, the expense is recorded over the remaining service period after the point when the achievement of the milestone is probable or the performance condition has been achieved. For stock option grants for which vesting is subject to both performance-based milestones and market conditions, expense is recorded over the derived service period after the point when the achievement of the performance-based milestone is probable or the performance condition has been achieved. The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model, with the exception of option grants for which vesting is subject to both performance-based milestones and market conditions, which are valued using a lattice-based model. The fair value of restricted stock units is based on the closing price of the Company's common stock as reported on The Nasdaq Global Market on the date of grant. The Company recognizes forfeitures for all awards as such forfeitures occur.

#### **Convertible Preferred Stock**

The Company applies the relevant accounting standards to distinguish liabilities from equity when assessing the classification and measurement of preferred stock. Preferred shares subject to mandatory redemptions are considered liabilities and measured at fair value. Conditionally redeemable preferred shares are considered temporary equity. All other preferred shares are considered as stockholders' equity.

The Company applies the relevant accounting standards for derivatives and hedging (in addition to distinguishing liabilities from equity) when accounting for hybrid contracts that contain conversion options. Conversion options must be bifurcated from the host instruments and accounted for as free-standing financial instruments according to certain criteria. These criteria include circumstances when (i) the economic characteristics and risks of the embedded derivative instruments are not clearly and closely related to the economic characteristics and risks of the host contract, (ii) the hybrid instrument that embodies both the embedded derivative instrument and the host contract is not re-measured at fair value under otherwise applicable accounting principles with changes in fair value reported in earnings as they occurred, and (iii) a separate instrument with the same terms as the embedded derivative instrument would be considered a derivative instrument. The derivative is subsequently measured at fair value at each reporting date, with the changes in fair value reported in earnings.

#### **Comprehensive Loss**

Comprehensive loss is defined as a change in equity during a period from transactions and other events and circumstances from non-owner sources. Other comprehensive loss includes unrealized gains and losses, other than losses attributable to a credit loss which are included in other income and expense, on investments classified as available-for-sale securities, which was the only difference between net loss and comprehensive loss for the applicable periods.

#### **Net Loss per Common Share**

Basic net loss per common share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding for the period, without consideration for common stock equivalents. Dilutive common stock equivalents for the periods presented include convertible preferred stock, warrants for the purchase of common stock, and common stock options and restricted stock units outstanding under the Company's stock option and incentive plans. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding due to the Company's net loss position.

For the three and six months ended June 30, 2020, the Company realized a net loss of \$28.1 million and \$61.6 million, respectively. Shares of potentially dilutive securities totaled 25.8 million for the three and six months ended June 30, 2020, including 14.0 million shares associated with a hypothetical conversion of all outstanding shares of the Company's Class A convertible preferred stock, and an aggregate of 11.8 million shares of common stock issuable upon the exercise of outstanding stock options and the settlement of outstanding restricted stock units.

For the three and six months ended June 30, 2019, the Company realized a net loss of \$23.5 million and \$43.2 million, respectively. Shares of potentially dilutive securities totaled 24.1 million for the three and six months ended June 30, 2019, including 14.1 million shares associated with a hypothetical conversion of all outstanding shares of the Company's Class A convertible preferred stock, and an aggregate of 9.9 million shares of common stock issuable upon the exercise of outstanding stock options and the settlement of outstanding restricted stock units.

#### **Going Concern Assessment**

Substantial doubt about an entity's ability to continue as a going concern exists when relevant conditions and events, considered in the aggregate, indicate that it is probable that the entity will be unable to meet its obligations as they become due within one year from the financial statement issuance date. The Company determined that there are no conditions or events that raise substantial doubt about its ability to continue as a going concern for a period of at least twelve months from the date of issuance of these financial statements.

#### **Recently Adopted Accounting Pronouncements**

In December 2019, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2019-12, *Simplifying the Accounting for Income Taxes*, which simplifies the accounting for income taxes by removing certain exceptions to the general principles in Accounting Standards Codification (ASC) Topic 740 and amends existing guidance to improve consistent application. ASU 2019-12 is effective for fiscal years beginning after December 15, 2020 and early adoption is permitted. The only exception addressed in ASU 2019-12 applicable to the Company is the elimination of the intra-period exception to allocating income taxes when there are losses from continuing operations. The guidance is to be applied prospectively at the beginning in the year of adoption. The Company elected to early adopt the standard as of January 1, 2020 using the prospective method, and such adoption did not have a material impact on the Company's consolidated financial statements.

In November 2018, the FASB issued ASU 2018-18, which clarifies the interaction between ASC Topic 808, *Collaborative Arrangements*, and ASC Topic 606, *Revenue from Contracts with Customers*. The guidance, among other items, clarifies that certain transactions between collaborative participants should be accounted for as revenue under Topic 606 when the collaborative arrangement participant is a customer in the context of a unit of account. ASU 2018-18 is effective for fiscal years beginning after December 15, 2019. The Company adopted the standard effective January 1, 2020, and such adoption did not have a material impact on the Company's consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820)*: *Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement*, which amends the disclosure requirements in ASC 820 by adding, changing, or removing certain disclosures. ASU 2018-13 is effective for fiscal years beginning after December 15, 2019. The Company adopted the standard effective January 1, 2020, and such adoption did not have a material impact on the Company's consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments – Credit Losses: Measurement of Credit Losses on Financial Instruments*, which amends the impairment model by requiring entities to use a forward-looking approach based on expected losses to estimate credit losses on certain types of financial instruments, including trade receivables and available-for-sale debt securities. The standard is effective for fiscal years beginning after December 15, 2019, with early adoption permitted. The Company adopted the standard effective January 1, 2020 using the modified retrospective approach. Due to the nature of the Company's investment portfolio, the adoption of the guidance did not have a material effect on the Company's unaudited condensed consolidated financial statements and no allowance was recorded for expected credit losses.

#### 2. Collaboration and License Agreements

#### **Janssen Collaboration and Option Agreement**

On April 2, 2020 (the Effective Date), the Company entered into a Collaboration and Option Agreement (the Janssen Agreement) with Janssen Biotech, Inc. (Janssen), part of the Janssen Pharmaceutical Companies of Johnson & Johnson. Additionally, on the Effective Date, the Company entered into a Stock Purchase Agreement (the Stock Purchase Agreement) with Johnson & Johnson Innovation – JJDC, Inc. (JJDC).

Upon entering the Janssen Agreement, the Company received an upfront, non-refundable and non-creditable payment of \$50.0 million. Under the Janssen Agreement, Janssen and the Company will collaborate to develop iPSC-derived CAR NK and CAR T-cell product candidates for the treatment of cancer. Janssen will contribute proprietary antigen binding domains directed to up to four tumor-associated antigen targets (the Janssen Cancer Targets). The Company will research and construct iPSC-derived CAR NK and CAR T-cell product candidates directed to each of the Janssen Cancer Targets (the Collaboration Candidates) and perform preclinical development of Collaboration Candidates. Upon the Company's completion of activities sufficient to allow the filing of an Investigational New Drug (IND) application for a Collaboration Candidate, Janssen will have the right to exercise an exclusive option and obtain an exclusive license to the Company's intellectual property rights for the development and commercialization of such Collaboration Candidate. Upon the exercise of such exclusive option, Janssen will be solely responsible for the worldwide clinical development and commercialization of such Collaboration Candidate, and the Company will be primarily responsible for the manufacture, at Janssen's cost, of such Collaboration Candidate. For each Collaboration Candidate, upon attaining clinical proof-of-concept, the Company shall have the right to elect to co-commercialize and share equally in the profits and losses in the United States, subject to the Company sharing in certain development costs.

Under the Stock Purchase Agreement, the Company sold 1.6 million shares of common stock to JJDC at \$31.00 per share, for an aggregate purchase price of approximately \$50.0 million, on April 7, 2020. The Company determined that this common stock purchase represented a premium of \$9.93 per share, or \$16.0 million in aggregate (the Equity Premium), and the remaining \$34.0 million was recorded as an issuance of common stock in shareholders' equity.

In addition, under the Stock Purchase Agreement, the Company had the right to require that JJDC purchase an aggregate of \$50.0 million in shares of the Company's common stock in a private placement at the same price per share as that paid by investors in a public offering. In June 2020, in connection with the Company's June 2020 public offering, the Company exercised this right and JJDC purchased in a private placement 1.8 million shares of the Company's common stock at a price of \$28.31 per share, for aggregate proceeds of \$50.0 million.

Under the terms of the Janssen Agreement, the Company is entitled to receive full funding for all research, preclinical development and IND-enabling activities performed by the Company for Collaboration Candidates, and is eligible to receive (i) with respect to the first Janssen Cancer Target, payments of up to \$898.0 million upon the achievement of specified development, regulatory and sales milestones (the Janssen Milestone Payments) for the first Collaboration Candidate, and up to \$460.0 million in Janssen Milestone Payments for each additional Collaboration Candidate, directed to the first Janssen Cancer Target; and (ii) with respect to each of the second, third and fourth Janssen Cancer Targets, up to \$706.0 million in Janssen Milestone Payments for each additional Collaboration Candidate, directed to the applicable Janssen Cancer Target, where certain Janssen Milestone Payments under (i) and (ii) are subject to reduction in the event the Company elects to co-commercialize and share equally in the profits and losses in the United States of a respective Collaboration Candidate. The Company is further eligible to receive double-digit tiered royalties ranging up to the mid-teens on net sales of Collaboration Candidates that are commercialized by Janssen under the Janssen Agreement, subject to reduction under certain circumstances.

Janssen may terminate the Janssen Agreement with respect to one or more Janssen Cancer Targets, or in its entirety, at any time on or after the second anniversary of the Effective Date, and the Company may terminate the Janssen Agreement with respect to a particular Janssen Cancer Target if a Collaboration Candidate has not been selected for IND-enabling studies for such Janssen Cancer Target within specified time periods under certain conditions. The Janssen Agreement contains customary provisions for termination by either party in the event of a material breach of the Janssen Agreement, subject to cure, by the other party and in the event of any bankruptcy, insolvency or similar events with respect to the other party.

The Company applied ASC 808, *Collaborative Arrangements* and determined the Janssen Agreement is applicable to such guidance. The Company concluded that Janssen represented a customer and applied relevant guidance from ASC 606, *Revenue from Contracts with Customers* (ASC 606) to evaluate the appropriate accounting for the Janssen Agreement. In accordance with this guidance, the Company identified its potential performance obligations, including its grant of a license to Janssen to certain of its intellectual property subject to certain conditions, its conduct of research and development services, and its participation in various joint oversight committees. The Company determined that its grant of a license to Janssen to certain of its intellectual property subject to certain conditions was not distinct from other performance obligations because such grant is dependent on the conduct and results of the research and development services. Accordingly, the Company determined that its grant of a license to Janssen and its conduct of research and development services should be accounted for as one combined performance obligation, and that the combined performance obligation is transferred over the expected term of the conduct of the research and development services, which is estimated to be four years. Additionally, the Company determined that participation in the various joint oversight committees did not constitute a performance obligation as the Company's participation in the various joint oversight committees does not transfer a service.

The Company also assessed the effects of any variable elements under the Janssen Agreement. Such assessment evaluated, among other things, the funding to be received by the Company for its conduct of research and development services. Based on its assessment, the Company concluded that the total amount to be received by the Company for its conduct of research and development services is variable and cannot be readily estimated and, therefore, no amounts associated with such services were included in the transaction price. In addition, the Company also assessed its likelihood of receiving (i) preclinical milestones, (ii) various clinical, regulatory and commercial milestone payments, and (iii) royalties on net sales of the Collaboration Candidates. Based on the likelihood of receiving such milestone payments and royalties, no amounts associated with milestones or royalties were included in the transaction price.

In accordance with ASC 606, the Company determined that the initial transaction price under the Janssen Agreement equals \$66.0 million, consisting of the upfront, non-refundable and non-creditable payment of \$50.0 million and the Equity Premium of \$16.0 million. The Company concluded that there was not a significant financing component under the Janssen Agreement. The upfront payment of \$66.0 million was recorded as deferred revenue and is being recognized as revenue consistent with the Company's efforts related to the conduct of research and development services, as the research and development services are the primary component of the combined performance obligation. Since the total amount to be received by the Company for its research and development services under the Janssen Agreement could not be readily estimated, revenue associated with the upfront payment will be recognized based on actual headcount utilized as a percentage of total headcount expected to be utilized over the expected term of conduct of the research and development services. Revenue associated with the research and development services will be recognized in an amount equal to the actual costs incurred during the period in which the research and development services are performed by the Company.

As a direct result of the Company's entry into the Janssen Agreement, the Company incurred \$13.3 million in sublicense fees to certain of its existing licensors (of which \$4.3 million was paid as of June 30, 2020). The \$13.3 million in sublicense consideration represents an asset under ASC 340, *Other Assets and Deferred Costs* and is amortized to research and development expense ratably with the Company's revenue recognition under the Janssen Agreement. During the three and six months ended June 30, 2020, the Company recognized \$0.3 million of such expense. As of June 30, 2020, the Janssen Agreement contract asset balance was \$13.0 million.

The Company recognized revenue of \$3.5 million under the Janssen Agreement for both the three and six months ended June 30, 2020. Such revenue comprised \$1.7 million associated with research and development services and \$1.8 million associated with the upfront fee and Equity Premium for both the three and six months ended June 30, 2020. As of June 30, 2020, aggregate deferred revenue related to the Janssen Agreement was \$64.2 million, of which \$12.1 million is classified as current.

#### **Ono Collaboration and Option Agreement**

On September 14, 2018, the Company entered into a Collaboration and Option Agreement (the Ono Agreement) with Ono Pharmaceutical Co. Ltd. (Ono) for the joint development and commercialization of two off-the-shelf iPSC-derived chimeric antigen receptor (CAR) T-cell product candidates. The first off-the-shelf, iPSC-derived CAR T-cell candidate (Candidate 1) targets an antigen expressed on certain lymphoblastic leukemias, and the second off-the-shelf, iPSC-derived CAR T-cell candidate (Candidate 2) targets a novel antigen identified by Ono expressed on certain solid tumors (each a Candidate and collectively the Candidates).

Pursuant to the Ono Agreement, the Company and Ono are jointly conducting research and development activities under a joint development plan, with the goal of advancing each Candidate to a pre-defined preclinical milestone. The Company has granted to Ono, during a specified period of time, an option to obtain an exclusive license under certain intellectual property rights to develop and commercialize (a) Candidate 1 in Asia, with the Company retaining rights for development and commercialization in all other territories of the world and (b) Candidate 2 in all territories of the world, with the Company retaining the right to co-develop and co-commercialize Candidate 2 in the United States and Europe under a joint arrangement whereby it is eligible to share at least 50% of the profits and losses (each, an Option).

For each Candidate, the Option will expire upon the earliest of: (a) the achievement of the pre-defined preclinical milestone, (b) termination by Ono of research and development activities for the Candidate and (c) the date that is the later of (i) four years after the Effective Date and (ii) completion of all applicable activities contemplated under the joint development plan (the Option Period). The Company has maintained worldwide rights of manufacture for both Candidates.

Under the terms of the Ono Agreement, Ono paid the Company an upfront, non-refundable and non-creditable payment of \$10.0 million in connection with entering into the Ono Agreement. Additionally, as consideration for the Company's conduct of research and preclinical development under a joint development plan, Ono pays the Company annual research and development fees set forth in the annual budget included in the joint development plan, which fees are estimated to be \$20.0 million in aggregate over the course of the joint development plan.

Further, under the terms of the Ono Agreement, Ono has agreed to pay the Company up to an additional \$40.0 million, subject to the achievement of a preclinical milestone (Ono Option Milestone) and the exercise by Ono of the Options (Ono Option Exercise Fees) during the Option Period. Such fees are in addition to the upfront payment and research and development fees.

Subject to Ono's exercise of the Options and to the achievement of certain clinical, regulatory and commercial milestones (Ono Milestones) with respect to each Candidate in specified territories, the Company is eligible to receive an aggregate of up to \$285.0 million in milestone payments for Candidate 1 and an aggregate of up to \$895.0 million in milestone payments for Candidate 2, with the applicable milestone payments for Candidate 2 for the United States and Europe subject to reduction by 50% if the Company elects to co-develop and co-commercialize Candidate 2 as described above. The Company is also eligible to receive tiered royalties (Ono Royalties) ranging from the mid-single digits to the low-double digits based on annual net sales by Ono of each Candidate in specified territories, with such royalties subject to certain reductions.

The Ono Agreement will terminate with respect to a Candidate if Ono does not exercise its Option for a Candidate within the Option Period, or in its entirety if Ono does not exercise any of its Options for the Candidates within their respective Option Periods. In addition, either party may terminate the Ono Agreement in the event of breach, insolvency or patent challenges by the other party; provided, that Ono may terminate the Ono Agreement in its sole discretion (x) on a Candidate-by-Candidate basis at any time after the second anniversary of the effective date of the Ono Agreement or (y) on a Candidate-by-Candidate or country-by-country basis at any time after the expiration of the Option Period, subject to certain limitations. The Ono Agreement will expire on a Candidate-by-Candidate and country-by-country basis upon the expiration of the applicable royalty term, or in its entirety upon the expiration of all applicable payment obligations under the Ono Agreement.

The Company applied ASC 808 and determined that the Ono Agreement is applicable to such guidance. The Company concluded that Ono represented a customer and applied relevant guidance from ASC 606 to evaluate the appropriate accounting for the Ono Agreement. In accordance with this guidance, the Company identified its performance obligations, including its grant of a license to Ono to certain of its intellectual property subject to certain conditions, its conduct of research services, and its participation in a joint steering committee. The Company determined that its grant of a license to Ono to certain of its intellectual property subject to certain conditions was not distinct from other performance obligations because such grant is dependent on the conduct and results of the research services. Additionally, the Company determined that its conduct of research services was not distinct from other performance obligations since such conduct is dependent on the guidance of the joint steering committee. Accordingly, the Company determined that all performance obligations should be accounted for as one combined performance obligation, and that the combined performance obligation is transferred over the expected term of the conduct of the research services, which is estimated to be four years.

The Company also assessed, in connection with the upfront, non-refundable and non-creditable payment of \$10.0 million received in September 2018 and the \$5.0 million prepayment of the first-year research and development fees in October 2018 and concluded that there was not a significant financing component to the Ono Agreement.

The Company also assessed the effects of any variable elements under the Ono Agreement. Such assessment evaluated, among other things, the likelihood of receiving (i) preclinical milestone and option fees, (ii) various clinical, regulatory and commercial milestone payments, and (iii) royalties on net sales of either product Candidate. Based on its assessment, the Company concluded that, based on the likelihood of these variable components occurring, there was not a significant variable element included in the transaction price. Accordingly, the Company has not assigned a transaction price to any Ono Milestone, Ono Milestones or Ono Option Exercise Fees given the substantial uncertainty related to their achievement and has not assigned a transaction price to any Ono Royalties.

In accordance with ASC 606, the Company determined that the initial transaction price under the Ono Agreement equals \$30.0 million, consisting of the upfront, non-refundable and non-creditable payment of \$10.0 million and the aggregate estimated research and development fees of \$20.0 million. The upfront payment of \$10.0 million was recorded as deferred revenue and is being recognized as revenue over time in conjunction with the Company's conduct of research services as the research services are the primary component of the combined performance obligations. Revenue associated with the upfront payment will be recognized based on actual costs incurred as a percentage of the estimated total costs expected to be incurred over the expected term of conduct of the research services. The Company recorded the \$5.0 million prepayment of the first-year research and development fees as deferred revenue, and such fees were recognized as revenue as the research services were delivered.

The Company has not assigned a transaction price to any Ono Option Milestone, Ono Milestones or Ono Option Exercise Fees given the substantial uncertainty related to their achievement and has not assigned a transaction price to any Ono Royalties.

As a direct result of the Company's entry into the Ono Agreement, the Company incurred an aggregate of \$2.0 million in sublicense consideration to existing licensors of the Company. The \$2.0 million in sublicense consideration represents an asset under ASC 340, *Other Assets and Deferred Costs* and is being amortized to research and development expense ratably with the Company's revenue recognition under the Ono Agreement. During the three months ended June 30, 2020 and 2019, the Company recognized \$0.1 million and \$0.2 million of such expense, respectively, and during the six months ended June 30, 2020 and 2019, the Company recognized \$0.3 million and \$0.3 million of such expense, respectively. As of June 30, 2020, the Ono Agreement contract asset balance was \$1.0 million.

The Company recognized revenue of \$2.0 million and \$4.5 million under the Ono Agreement for the three and six months ended June 30, 2020, respectively. Such revenue comprised \$1.3 million associated with research services and \$0.7 million associated with the upfront payment for the three months ended June 30, 2020, and \$3.0 million associated with research services and \$1.5 million associated with the upfront payment for the six months ended June 30, 2020. During the three and six months ended June 30, 2019, the Company recognized revenue of \$2.5 million and \$4.1 million under the Ono Agreement, respectively. Such revenue comprised \$1.7 million associated with research services and \$0.8 million associated with the upfront payment for the three months ended June 30, 2019, and \$2.7 million associated with research services and \$1.4 million associated with the upfront payment for the six months ended June 30, 2019. As of June 30, 2020, aggregate deferred revenue related to the Ono Agreement was \$5.1 million, of which \$2.5 million is classified as current.

As of June 30, 2020, the Company has received \$9.5 million in aggregate research and development fees from Ono.

#### Juno Collaboration and License Agreement

On May 4, 2015, the Company entered into a strategic research collaboration and license agreement (the Juno Agreement) with Juno Therapeutics, Inc. (Juno) to screen for and identify small molecules that enhance the therapeutic properties of Juno's genetically-engineered T-cell immunotherapies. The four-year initial research term under the Juno Agreement concluded as scheduled on May 4, 2019, and the overall agreement was terminated upon the receipt of the last quarterly research payment of \$0.2 million, which occurred in May 2019.

No revenue was recognized under the Juno Agreement for the three and six months ended June 30, 2020. During the three and six months ended June 30, 2019 was \$0.4 million and \$1.4 million, respectively, under the Juno Agreement. No additional revenue is expected to be recognized under the Juno Agreement in future periods.

#### 3. California Institute for Regenerative Medicine Award

On April 5, 2018, the Company executed an award agreement with the California Institute for Regenerative Medicine (CIRM) pursuant to which CIRM awarded the Company \$4.0 million to advance the Company's FT516 product candidate into a first-in-human clinical trial for the treatment of subjects with advanced solid tumors, including in combination with monoclonal antibody therapy (the Award). Pursuant to the terms of the Award, the Company is eligible to receive five disbursements in varying amounts totaling \$4.0 million, with one disbursement receivable upon the execution of the Award, and four disbursements receivable upon the completion of certain milestones throughout the project period. The Award is subject to certain cofunding requirements by the Company, and the Company is required to provide CIRM progress and financial update reports under the Award.

Pursuant to the terms of the Award, the Company, in its sole discretion, has the option to treat the Award either as a loan or as a grant. In the event the Company elects to treat the Award as a loan, the Company will be obligated to repay (i) 60%, (ii) 80%, (iii) 100% or (iv) 100% plus interest at 7% plus LIBOR, of the total Award to CIRM, where such repayment rate is dependent upon the phase of clinical development of FT516 at the time of the Company's election. If the Company does not elect to treat the Award as a loan within 10 years of the date of the Award, the Award will be considered a grant and the Company will be obligated to pay to CIRM a royalty on commercial sales of FT516 until such royalty payments equal nine times the total amount awarded to the Company under the Award.

Since the Company may, at its election, repay some or all of the Award, the Company accounts for the Award as a liability until the time of election. As of June 30, 2020, the Company has received aggregate disbursements under the Award in the amount of \$4.0 million. The aggregate amount received is recorded as a CIRM Liability on the accompanying unaudited condensed consolidated balance sheets and classified as current or non-current based on the potential amount payable within twelve months of the current balance sheet.

#### 4. Investments

The Company invests portions of excess cash in United States treasuries and corporate debt securities with maturities ranging from three to eighteen months from the purchase date. These securities are classified as short-term and long-term investments in the accompanying unaudited condensed consolidated balance sheets based on each security's contractual maturity date and are accounted for as available-for-sale securities.

The following table summarizes the Company's investments accounted for as available-for-sale securities as of June 30, 2020 and December 31, 2019 (in thousands):

	Maturity (in years)	Amortized Cost												Jnrealized Gains	ed Estimated Fair Value	
June 30, 2020																
Classified as current assets:																
U.S. Treasury debt securities	1 or less	\$	34,349	\$ _	\$	171	\$	34,520								
Corporate debt securities	1 or less		65,363	_		452		65,815								
Total short-term investments		\$	99,712	\$	\$	623	\$	100,335								
December 31, 2019																
Classified as current assets:																
U.S. Treasury debt securities	1 or less	\$	50,445	\$ (4)	\$	16	\$	50,457								
Corporate debt securities	1 or less		71,171	(24)		9		71,156								
Total short-term investments		\$	121,616	\$ (28)	\$	25	\$	121,613								
Classified as non-current assets:																
U.S. Treasury debt securities	Greater than															
	1	\$	9,841	\$ _	\$	5	\$	9,846								
Corporate debt securities	Greater than															
	1		29,572	(1)		23		29,594								
Total long-term investments		\$	39,413	\$ (1)	\$	28	\$	39,440								

The Company reviews its investment holdings at the end of each reporting period and evaluates any unrealized losses using the expected credit loss model to determine if the unrealized loss is a result of a credit loss or other factors. The Company also evaluates its investment holdings for impairment using a variety of factors including the Company's intent to sell the underlying securities prior to maturity and whether it is more likely than not that the Company would be required to sell the securities before the recovery of their amortized basis. During each of the three and six months ended June 30, 2020 and 2019, the Company did not recognize any impairment or realized gains or losses on sales of investments, and the Company did not record an allowance for, or recognize, any expected credit losses.

#### 5. Fair Value Measurements

The carrying amounts of accounts payable and accrued liabilities are considered to be representative of their respective fair values because of the short-term nature of those instruments. Based on the borrowing rates available to the Company for loans with similar terms, which is considered a Level 2 input as described below, the Company believes that the fair value of long-term debt approximated its carrying value during the periods the debt was outstanding.

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets;

Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

Financial assets measured at fair value on a recurring basis consist of the Company's cash equivalents and investments. Cash equivalents consisted of money market funds and investments consisted of United States treasuries and corporate debt securities. The following table presents the Company's assets which were measured at fair value on a recurring basis as of June 30, 2020 and December 31, 2019 (in thousands):

			Fair Value Measurements at Reporting Date Using											
	Total		Total		Total		Quoted Prices in Active Markets for Identical Assets (Level 1)		in Active Markets for Identical Assets			Significant Other Observable Inputs (Level 2)	Uno	gnificant observable Inputs Level 3)
As of June 30, 2020:	_													
Cash equivalents														
Money market funds	\$	433,074	\$	433,074	\$	_	\$	_						
Investments														
U.S. Treasury debt securities		34,520		34,520		_		_						
Corporate debt securities		65,815		_		65,815		_						
Total assets measured at fair value on a recurring basis	\$	533,409	\$	467,594	\$	65,815	\$							
As of December 31, 2019														
Cash equivalents														
Money market funds	\$	84,814	\$	84,814		_	\$	_						
Investments														
U.S. Treasury debt securities		60,303		60,303		_		_						
Corporate debt securities		100,750		_		100,750		_						
Total assets measured at fair value on a recurring basis	\$	245,867	\$	145,117	\$	100,750	\$							

The Company obtains pricing information from quoted market prices from its investment manager and generally determines the fair value of investment securities using standard observable inputs, including reported trades, broker/dealer quotes, and bids and/or offers.

None of the Company's non-financial assets or liabilities are recorded at fair value on a non-recurring basis. No transfers between levels have occurred during the periods presented.

As of June 30, 2020, and December 31, 2019, the Company had no material financial liabilities measured at fair value on a recurring basis.

#### 6. Accrued Expenses and Long-Term Debt

#### **Accrued Expenses**

Current accrued expenses consist of the following (in thousands):

	<u> </u>	June 30, 2020	De	cember 31, 2019
Accrued payroll and other employee benefits	\$	4,371	\$	5,329
Accrued clinical trial related costs		4,098		5,976
Accrued other		3,149		3,392
Total current accrued expenses	\$	11,618	\$	14,697

#### Long-Term Debt

Silicon Valley Bank Debt

In 2009, the Company entered into a Loan and Security Agreement with Silicon Valley Bank, which was collateralized by substantially all of the Company's assets excluding certain intellectual property. This Loan and Security Agreement was subsequently amended in 2014 and in 2017. On November 13, 2019, the Company repaid in full all outstanding obligations under the Loan and Security Agreement, as amended. The Company used cash on hand in the amount of \$14.2 million for the repayment of such obligations, including the repayment of \$13.0 million in principal and \$1.2 million associated with the final fee and outstanding interest.

For the three and six months ended June 30, 2019, the Company recorded \$0.4 million and \$0.8 million, respectively, in debt interest expense.

#### 7. Leases

The Company has lease agreements for office, laboratory and manufacturing spaces that are classified as operating leases on the unaudited condensed consolidated balance sheets. These leases have terms varying from one to approximately sixteen years, with renewal options of up to ten years, as well as early termination options. Extension and termination options are included in the total lease term when the Company is reasonably certain to exercise them. The leases are subject to additional variable charges, including common area maintenance, property taxes, property insurance and other variable costs. Given the variable nature of such costs, they are recognized as expense as incurred. Additionally, some of the Company's leases are subject to certain fixed fees which the Company has determined to be non-lease components. The Company has elected to combine and account for lease and non-lease components as a single lease component for purposes of determining the total future lease payments.

In January 2020, the Company entered into a lease agreement for certain office, laboratory and manufacturing spaces (the Premises), and such lease is accounted for as an operating lease. The Premises are located in San Diego, California and the Company intends to move its corporate headquarters to the Premises in the middle of 2021. Lease payments shall commence, subject to certain conditions, in May 2021 (the Rent Commencement Date) and the lease has a lease term of 15 years starting from the Rent Commencement Date. The Company has the option to extend the lease for two successive five-year periods. The Company also has a one-time option to terminate the lease after 10 years from the Rent Commencement Date, subject to payment of a \$30.0 million early termination fee. The landlord of the Premises is obligated to contribute an aggregate of up to \$29.8 million toward tenant improvements of the Premises. As of June 30, 2020, the Company had utilized \$4.9 million associated with the tenant improvements allowance and expects the remainder of the tenant improvements to be utilized within the next twelve months. In connection with the lease, the Company maintains a letter of credit for the benefit of the landlord in an amount equal to \$15.0 million, which amount is subject to reduction over time.

As of June 30, 2020, future undiscounted minimum contractual payments under the Company's operating leases were \$195.1 million, which will be paid over a remaining weighted-average lease term of 13.4 years. The weighted-average discount rate for the operating lease liabilities was 8.4%, which was the Company's incremental borrowing rate at lease commencement, as the discount rates implicit in the leases could not be readily determined.

The components of lease expense were as follows:

	Three Months Ended June 30,			Six Mont Jun	hs En e 30,	ıded
	2020		2019	2020		2019
Straight-line lease expense	\$ 2,972	\$	945	\$ 5,910	\$	1,890
Variable lease expense	415		567	1,025		1,154
Total operating lease expense	\$ 3,387	\$	1,512	\$ 6,935	\$	3,044

Total lease expense associated with short-term leases was \$0.2 million for both the three months ended June 30, 2020 and 2019. Total lease expense associated with short-term leases for the six months ended June 30, 2020 and 2019 was \$0.7 million and \$0.2 million, respectively.

Future minimum lease payments under the Company's operating leases as of June 30, 2020 are as follows (in thousands):

	Operating ase Payments
Remaining in 2020	\$ 2,159
2021	9,741
2022	12,610
2023	12,988
2024	13,378
2025	13,779
Thereafter	130,446
Total undiscounted lease payments	\$ 195,101
Less: imputed interest	(89,111)
Less: amounts associated with tenant improvement allowance not yet utilized	(24,952)
Total lease liability	\$ 81,038

#### 8. Convertible Preferred Stock and Stockholders' Equity

#### **Convertible Preferred Stock**

In November 2016, the Company completed a private placement of stock in which investors, including investors affiliated with the directors and officers of the Company, purchased convertible preferred stock and common stock of the Company (the November 2016 Placement). The Company issued 2,819,549 shares of non-voting Class A Convertible Preferred Stock (the Class A Preferred) at \$13.30 per share, each of which is convertible into five shares of common stock upon certain conditions defined in the Certificate of Designation of Preferences, Rights and Limitations of the Class A Preferred with the Delaware Secretary of State on November 22, 2016 (the CoD). The Class A Preferred were purchased exclusively by entities affiliated with Redmile Group, LLC (collectively, Redmile). The terms of the CoD prohibited Redmile from converting the Class A Preferred into shares of the Company's common stock if, as a result of conversion, Redmile, together with its affiliates, would own more than 9.99% of the Company's common stock then issued and outstanding (the Redmile Percentage Limitation), which percentage could change at Redmile's election upon 61 days' notice to the Company to (i) any other number less than or equal to 19.99% or (ii) subject to approval of the Company's stockholders to the extent required in accordance with the Nasdaq Global Market rules, any number in excess of 19.99%. On May 2, 2017, the Company's stockholders approved the issuance of up to an aggregate of 14,097,745 shares of common stock upon the conversion of the outstanding shares of Class A Preferred. As a result, Redmile has the right to increase the Redmile Percentage Limitation to any percentage in excess of 19.99% at its election. The Company also issued 7,236,837 shares of common stock at \$2.66 per share as part of the November 2016 Placement.

The Class A Preferred are non-voting shares and have a stated par value of \$0.001 per share and are convertible into five shares of the Company's common stock at a conversion price of \$2.66 per share, which was the fair value of the Company's common stock on the date of issuance. Holders of the Class A Preferred have the same dividend rights as holders of the Company's common stock. Additionally, the liquidation preferences of the Class A Preferred are *pari passu* among holders of the Company's common stock and holders of the Class A Preferred, pro rata based on the number of shares held by each such holder (treated for this purpose as if the Class A Preferred had been converted to common stock).

During the year ended December 31, 2019, 25,000 shares of the Class A Preferred were converted into 125,000 shares of the Company's common stock.

#### **Stock Options and Restricted Stock Units**

Stock option activity under all equity and stock option plans is summarized as follows:

	Number of Options	Weighted- Average Price		
Balance at December 31, 2019	9,327,742	\$ 9.67		
Granted	1,796,588	23.03		
Exercised	(499,042)	7.04		
Cancelled	(166,100)	16.03		
Balance at June 30, 2020	10,459,188	\$ 11.99		

Restricted stock unit activity under all equity and stock option plans is summarized as follows:

	Number of Restricted Stock Units	Average C Fair Va	hted- Grant Date alue per are
Balance at December 31, 2019	520,000	\$	16.41
Granted	979,323		21.95
Vested	(85,000)		16.34
Cancelled	(33,706)		21.94
Balance at June 30, 2020	1,380,617	\$	20.21

The allocation of stock-based compensation for all stock awards is as follows (in thousands):

	Three Months Ended June 30,					Six Months Ended June 30,				
		2020		2019		2020	2019			
Research and development	\$	4,360	\$	2,479	\$	8,613	\$	4,662		
General and administrative		2,876		1,907		5,536		3,592		
Total	\$	7,236	\$	4,386	\$	14,149	\$	8,254		

As of June 30, 2020, the unrecognized compensation cost related to outstanding options was \$54.0 million and is expected to be recognized as expense over a weighted-average period of approximately 2.8 years.

As of June 30, 2020, the unrecognized compensation cost related to restricted stock units was \$23.3 million which is expected to be recognized as expense over a weighted-average period of approximately 3.2 years.

The weighted-average assumptions used in the Black-Scholes option pricing model to determine the fair value of the employee and nonemployee stock option grants were as follows:

	Six Months Ei June 30,	nded
	2020	2019
Risk-free interest rate	1.4%	2.5%
Expected volatility	77.2%	79.8%
Expected term (in years)	5.6	6.1
Expected dividend yield	0.0%	0.0%

### **Reconciliation of Consolidated Stockholders' Equity Accounts**

The following table summarizes the Company's changes in stockholders' equity accounts for the three and six months ended June 30, 2020 (in thousands, except share data):

	Convertible Preferred Stock		Common Stock			Accumulated Additional Other Paid-in Comprehensive			Accumulated	Sto	Total ockholders'													
	Shares	An	nount	Shares		Shares		Shares		Shares		Shares		Shares		Shares		mount	Capital		Gain	Deficit		Equity
Balance at December 31, 2019	2,794,549	\$	3	75,730,260	\$	76	\$ 628,200	\$	22	\$ (383,545)	\$	244,756												
Exercise of stock options, net of issuance costs	_		_	188,315		_	949			_		949												
Issuance of common stock upon vesting of restricted stock units	_		_	77,500		_	_		_	_		_												
Stock-based compensation							6,913					6,913												
Unrealized gain on investments	_		_	_		_	_		120	_		120												
Net loss	_		_	_		_	_		_	(33,520)		(33,520)												
Balance at March 31, 2020	2,794,549	\$	3	75,996,075	\$	76	\$ 636,062	\$	142	\$ (417,065)	\$	219,218												
Exercise of stock options, net of issuance costs				310,727		_	2,548					2,548												
Issuance of common stock upon vesting of restricted stock units	_		_	7,500		_	_		_	_		_												
Stock-based compensation	_		_	_		_	7,236		_	_		7,236												
Public offering of common stock, net of issuance costs	_		_	7,108,796		7	188,784		_	_		188,791												
Private placement of common stock, net of issuance costs	_		_	1,766,160		2	49,973		_	_		49,975												
Issuance of stock to collaboration partner, net of issuance costs	_		_	1,612,904		2	33,932		_	_		33,934												
Unrealized gain on investments			_			_			481			481												
Net loss			_			_			_	(28,072)		(28,072)												
Balance at June 30, 2020	2,794,549	\$	3	86,802,162	\$	87	\$ 918,535	\$	623	\$ (445,137)	\$	474,111												

The following table summarizes the Company's changes in stockholders' equity accounts for the three and six months ended June 30, 2019 (in thousands, except share data):

	Conver Preferred			Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Sto	Total ockholders'	
	Shares	Ame	ount	Shares	F	Amount	Capital	Gain (Loss)	Deficit		Equity
Balance at December 31, 2018	2,819,549	\$	3	64,693,681	\$	65	\$ 445,799	\$ (2)	\$ (285,396)	\$	160,469
Exercise of stock options, net of issuance costs			_	420,920		_	1,258				1,258
Issuance of common stock upon cashless warrant exercise	_		_	1,245		_	_	_	_		_
Stock-based compensation	_		_	_		_	3,868	_	_		3,868
Unrealized gain on investments	_		_	_		_	_	2	_		2
Net loss	_		_	_		_	_	_	(19,760)		(19,760)
Balance at March 31, 2019	2,819,549	\$	3	65,115,846	\$	65	\$ 450,925	\$ —	\$ (305,156)	\$	145,837
Exercise of stock options, net of issuance costs				194,045			688				688
Stock-based compensation	_		_	_		_	4,386	_	_		4,386
Unrealized gain on investments	_		_	_		_	_	93	_		93
Net loss	_		_	_		_	_	_	(23,478)		(23,478)
Balance at June 30, 2019	2,819,549	\$	3	65,309,891	\$	65	\$ 455,999	\$ 93	\$ (328,634)	\$	127,526

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

The following discussion and analysis should be read in conjunction with our financial statements and accompanying notes included in this Quarterly Report on Form 10-Q and the financial statements and accompanying notes thereto for the fiscal year ended December 31, 2019 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, which are contained in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 2, 2020.

This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). Such forward-looking statements, which represent our intent, belief, or current expectations, involve risks and uncertainties and other factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. In some cases you can identify forward-looking statements by terms such as "may," "will," "expect," "anticipate," "estimate," "intend," "plan," "predict," "potential," "believe," "should" and similar expressions. Factors that could cause or contribute to differences in results include, but are not limited to, those set forth under "Risk Factors" under Item 1A of Part II below. Except as required by law, we undertake no obligation to update these forward-looking statements to reflect events or circumstances after the date of this report or to reflect actual outcomes.

#### Overview

We are a clinical-stage biopharmaceutical company dedicated to the development of programmed cellular immunotherapies for cancer and immune disorders. We are developing first-in-class cell therapy product candidates based on a simple notion: we believe that better cell therapies start with better cells.

To create better cell therapies, we use a therapeutic approach that we generally refer to as cell programming. For certain of our product candidates, we use pharmacologic modulators, such as small molecules, to enhance the biological properties and therapeutic function of healthy donor-sourced cells ex vivo before our product candidates are administered to a patient. In other cases, we use human induced pluripotent stem cells (iPSCs) to generate a clonal master iPSC line having preferred biological properties and direct the fate of the clonal master iPSC line to create our cell therapy product candidate. Analogous to master cell lines used to manufacture biopharmaceutical drug products such as monoclonal antibodies, we believe clonal master iPSC lines can be used as a renewable source for manufacturing cell therapy products which are well-defined and uniform in composition, can be repeatedly mass produced at significant scale in a cost-effective manner, and can be delivered off-the-shelf to treat many patients. Utilizing these therapeutic approaches, we program cells of the blood and immune system, including natural killer (NK) cells, T cells and CD34+ cells, and are advancing a pipeline of programmed cellular immunotherapies.

We have entered into a research collaboration and license agreement with the Regents of the University of Minnesota to develop off-the-shelf, engineered NK cell cancer immunotherapies derived from clonal master iPSC lines. Additionally, we have entered into a research collaboration and license agreement with Memorial Sloan Kettering Cancer Center (Memorial Sloan Kettering) to develop off-the-shelf, engineered T-cell cancer immunotherapies derived from clonal master iPSC lines.

We have entered into a collaboration and option agreement with Ono Pharmaceutical Co. Ltd. (Ono) for the joint development and commercialization of two off-the-shelf iPSC-derived chimeric antigen receptor (CAR) T-cell product candidates (Ono Agreement).

In April 2020, we entered into a collaboration and option agreement with Janssen Biotech, Inc. (Janssen), part of the Janssen Pharmaceutical Companies of Johnson & Johnson (Janssen Agreement). Under the Janssen Agreement, we and Janssen will collaborate to develop iPSC-derived CAR NK and CAR T-cell product candidates for the treatment of cancer.

We were incorporated in Delaware in 2007, and are headquartered in San Diego, CA. Since our inception in 2007, we have devoted substantially all of our resources to our cell programming approach and the research and development of our product candidates, the creation, licensing and protection of related intellectual property, and the provision of general and administrative support for these activities. To date, we have funded our operations primarily through the public and private sale of common stock, the private placement of preferred stock and convertible notes, commercial bank debt and revenues from collaboration activities and grants.

We have never been profitable and have incurred net losses in each year since inception. Substantially all of our net losses resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to continue to incur operating losses for at least the foreseeable future. Our net losses may fluctuate significantly from quarter to quarter and year to year. We expect our expenses will increase substantially in connection with our ongoing and planned activities as we:

- conduct our ongoing and planned clinical trials of our product candidates;
- conduct GMP production, process and scale-up development and technology transfer activities for the manufacture of our product candidates, including those undergoing clinical investigation and IND-enabling preclinical development;

- procure laboratory equipment, materials and supplies for the manufacture of our product candidates and the conduct of our research activities;
- conduct preclinical and clinical research to investigate the therapeutic activity of our product candidates;
- continue our research, development and manufacturing activities, including under our sponsored research and collaboration agreements with Janssen, Ono, University of Minnesota and Memorial Sloan Kettering;
- maintain, prosecute, protect, expand and enforce our intellectual property portfolio;
- engage with regulatory authorities for the development of, and seek regulatory approvals for, our product candidates;
- establish business operations at our new corporate headquarters, including design and build of laboratory space and internal GMP production capabilities;
- hire additional clinical, manufacturing, regulatory, quality control and technical personnel to advance our product candidates;
- hire additional scientific personnel to advance our research and development efforts; and
- hire general and administrative personnel to continue operating as a public company and support our operations.

We do not expect to generate any revenues from sales of any therapeutic products unless and until we successfully complete development and obtain regulatory approval for one or more of our product candidates, which we expect will take a number of years. If we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, we will seek to fund our operations through public or private equity or debt financings or other sources. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements when needed would have a negative effect on our financial condition and ability to develop our product candidates.

Due to the global outbreak of SARS-CoV-2, the novel strain of coronavirus that causes Coronavirus disease 19 (COVID-19), we experienced impacts on certain aspects of our business, including our clinical trial and research and development activities, during the six months ended June 30, 2020. For example, certain of our research and development activities have been delayed or disrupted as a result of measures we have implemented in response to governmental "stay at home" orders and in the interests of public health and safety, and we have experienced delays or disruptions in the initiation and conduct of our clinical trials as a result of prioritization of hospital and other medical resources toward pandemic efforts, policies and procedures implemented at clinical sites with respect to the conduct of clinical trials, and other precautionary measures taken in treating patients or in practicing medicine in response to the COVID-19 pandemic. The scope and duration of these delays and disruptions, and the ultimate impacts of COVID-19 on our operations, are currently unknown. We are continuing to actively monitor the situation and may take further precautionary and preemptive actions as may be required by federal, state or local authorities or that we determine are in the best interests of public health and safety and that of our patient community, employees, partners, and stockholders. We cannot predict the effects that such actions, or the impact of COVID-19 on global business operations and economic conditions, may have on our business, strategy, collaborations, or financial and operating results.

#### **Financial Operations Overview**

We conduct substantially all of our activities through Fate Therapeutics, Inc., a Delaware corporation, at our facilities in San Diego, California. Fate Therapeutics, Inc. owns 100% of the voting shares of Tfinity Therapeutics, Inc. (Tfinity), incorporated in the United States, 100% of the voting shares of Fate Therapeutics Ltd. (Fate Ltd.), incorporated in the United Kingdom, and 100% of the voting shares of Fate Therapeutics B.V. (Fate B.V.), incorporated in the Netherlands. The following information is presented on a consolidated basis to include the accounts of Fate Therapeutics, Inc., Tfinity, Fate B.V., and Fate Ltd. To date, the aggregate operations of our subsidiaries have not been significant and all intercompany transactions and balances have been eliminated in consolidation.

#### Collaboration Revenue

To date, we have not generated any revenues from therapeutic product sales. Our revenues have been derived from collaboration agreements and government grants.

Agreement with Janssen Biotech, Inc.

On April 2, 2020 (the Effective Date), we entered into a Collaboration and Option Agreement (the Janssen Agreement) with Janssen Biotech, Inc. (Janssen), part of the Janssen Pharmaceutical Companies of Johnson & Johnson. Additionally, on the Effective Date, we entered into a Stock Purchase Agreement (the Stock Purchase Agreement) with Johnson & Johnson Innovation - JJDC, Inc. (JJDC). Under the terms of the Janssen Agreement and the Stock Purchase Agreement taken together, we received \$100.0 million, of which \$50.0 million is an upfront cash payment and \$50.0 million is in the form of an equity investment by JJDC. Additionally, we are entitled to receive fees for the conduct of all research, preclinical development and IND-enabling activities performed by us under the Janssen Agreement.

We determined the common stock purchase by JJDC represented a premium of \$9.93 per share, or \$16.0 million in aggregate (the Equity Premium), and the remaining \$34.0 million was recorded as issuance of common stock in shareholders' equity.

We concluded that Janssen represented a customer and in accordance with Accounting Standards Codification (ASC) 606, *Revenue from Contracts with Customers*, we determined that the initial transaction price under the Janssen Agreement equals \$66.0 million, consisting of the upfront, non-refundable and non-creditable payment of \$50.0 million and the Equity Premium of \$16.0 million. In addition, we identified our potential performance obligations under the Janssen Agreement, including our grant to Janssen of a license to certain of our intellectual property subject to certain conditions, our conduct of research and development services, and our participation in various joint oversight committees. We determined that our grant of a license to Janssen and our conduct of research and development services should be accounted for as one combined performance obligation, and that the combined performance obligation is transferred over the expected term of the conduct of the research and development services, which is estimated to be four years. Additionally, we determined that participation in the various joint oversight committees did not constitute a performance obligation as our participation in the various joint oversight committees did not constitute a performance obligation as our participation in

During both the three and six months ended June 30, 2020, we recognized \$3.5 million of collaboration revenue under the Janssen Agreement. As of June 30, 2020, aggregate deferred revenue related to the Janssen Agreement was \$64.2 million.

Agreement with Ono Pharmaceutical Co., Ltd.

On September 14, 2018, we entered into a Collaboration and Option Agreement (the Ono Agreement) with Ono for the joint development and commercialization of two off-the-shelf iPSC-derived CAR T-cell product candidates. Pursuant to the terms of the Ono Agreement, we received an upfront, non-refundable and non-creditable payment of \$10.0 million. Additionally, we are entitled to receive fees for the conduct of research and development under a joint development plan, which fees are estimated to be \$20.0 million in aggregate.

We concluded that Ono represented a customer and in accordance with ASC 606, we determined that the initial transaction price under the Ono Agreement equals \$30.0 million, consisting of the upfront, non-refundable and non-creditable payment of \$10.0 million and the aggregate estimated research and development fees of \$20.0 million. In addition, we identified our performance obligations under the Ono Agreement, including our grant to Ono of a license to certain of our intellectual property subject to certain conditions, our conduct of research services, and our participation in a joint steering committee. We determined that all performance obligations should be accounted for as one combined performance obligation, and that the combined performance obligation is transferred over the expected term of the conduct of the research services, which is estimated to be four years.

During the three and six months ended June 30, 2020, we recognized \$2.0 million and \$4.5 million, respectively, of collaboration revenue under the Ono Agreement. During the three and six months ended June 30, 2019, we recognized \$2.5 million and \$4.1 million, respectively, of collaboration revenue under the Ono Agreement. As of June 30, 2020, aggregate deferred revenue related to the Ono Agreement was \$5.1 million.

Agreement with Juno Therapeutics, Inc.

On May 4, 2015, we entered into a strategic research collaboration and license agreement (the Juno Agreement) with Juno Therapeutics, Inc. (Juno) to screen for and identify small molecule modulators that enhance the therapeutic properties of Juno's genetically-engineered T-cell immunotherapies.

No revenue was recognized under the Juno Agreement for the three and six months ended June 30, 2020. During the three and six months ended June 30, 2019, we recognized \$0.4 million and \$1.4 million, respectively, of collaboration revenue under the Juno Agreement.

On May 4, 2019, the four-year initial research term under the Juno Agreement concluded as scheduled. The final quarterly research payment of \$0.2 million was received during May 2019 and no additional payments are expected.

#### Research and Development Expenses

Research and development expenses consist of costs associated with the research, preclinical development, process and scale-up development, manufacture and clinical development of our product candidates, the research and development of our cell programming technology including our iPSC product platform, and the performance of research and development activities under our collaboration agreements. These costs are expensed as incurred and include:

- salaries and employee-related costs, including stock-based compensation;
- costs incurred under clinical trial agreements with investigative sites;
- · costs to acquire, develop and manufacture preclinical study and clinical trial materials, including our product candidates;
- costs associated with conducting our preclinical, process and scale-up development, manufacturing, clinical and regulatory activities, including fees paid to third-party professional consultants, service providers and suppliers;
- costs incurred for our research, development and manufacturing activities, including under our collaboration agreements;
- costs for laboratory equipment, materials and supplies for the manufacture of our product candidates and the conduct of our research activities:
- costs incurred to license and maintain intellectual property; and
- facilities, depreciation and other expenses including allocated expenses for rent and maintenance of facilities.

We plan to increase our current level of research and development expenses for the foreseeable future as we continue the clinical and preclinical development of our product candidates, research and develop our cell programming technology including our iPSC product platform, and perform our obligations under collaboration agreements including under our agreements with Janssen, Ono, University of Minnesota and Memorial Sloan Kettering. Our current planned research and development activities over the next twelve months consist primarily of the following:

- initiating and conducting clinical trials of our product candidates;
- conducting GMP production, process and scale-up development and technology transfer activities for the manufacture of our product candidates, including those undergoing clinical investigation and IND-enabling preclinical development;
- procuring laboratory equipment, materials and supplies for the manufacture of our product candidates and the conduct of our research activities:
- conducting preclinical and clinical research to investigate the therapeutic activity of our product candidates; and
- conducting research, development and manufacturing activities, including under our sponsored research and collaboration agreements with Janssen, Ono, University of Minnesota and Memorial Sloan Kettering.

Due to the inherently unpredictable nature of preclinical and clinical development, and given our novel therapeutic approach and the current stage of development of our product candidates, we cannot determine and are unable to estimate with certainty the timelines we will require and the costs we will incur for the development of our product candidates. Clinical and preclinical development timelines and costs, and the potential of development success, can differ materially from expectations. In addition, we cannot forecast which product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements. We cannot predict the effects of the impact of COVID-19 on our business and operations, and our expenditures may be increased by delays or disruptions due to the COVID-19 pandemic, including as a result of actions we take in the near term to ensure business continuity and protect against possible supply chain shortages.

#### General and Administrative Expenses

General and administrative expenses consist primarily of salaries and employee-related costs, including stock-based compensation, for our employees in executive, operational, finance and human resource functions; professional fees for accounting, legal and tax services; costs for obtaining, prosecuting and maintaining our intellectual property; and other costs and fees, including director and officer insurance premiums, to support our operations as a public company. We anticipate that our general and administrative expenses will increase in the future as we increase our research and development activities, maintain compliance with exchange listing and SEC requirements and continue to operate as a public company.

#### Other Income (Expense)

Other income (expense) consists primarily of interest income earned on cash and cash equivalents, interest income from investments (including the amortization of discounts and premiums), and interest expense for the periods where debt was outstanding.

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

Our management's discussion and analysis of our financial condition and results of operations are based on our unaudited condensed consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles. The preparation of these unaudited condensed consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses and stock-based compensation. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

With the exception of our adoption of new credit impairment loss guidance, the estimates and judgments involved in our accounting policies as described in Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2019 continue to be our critical accounting policies and there have been no material changes to our critical accounting policies during the six months ended June 30, 2020.

See Note 1 to the unaudited condensed consolidated financial statements for a summary of critical accounting policies and information related to recent accounting pronouncements.

#### **Results of Operations**

#### Comparison of the Three Months Ended June 30, 2020 and 2019

The following table summarizes the results of our operations for the three months ended June 30, 2020 and 2019 (in thousands):

		Three Months			
	2020			2019	Increase
Collaboration revenue	\$	5,465	\$	2,817	\$ 2,648
Research and development expense		26,669		21,631	5,038
General and administrative expense		7,503		5,270	2,233
Total other income, net		635		606	29

*Revenue*. During the three months ended June 30, 2020, we recognized revenue of \$5.5 million under our collaboration agreements with Janssen and Ono. During the three months ended June 30, 2019, we recognized \$2.8 million under our collaboration agreements with Ono and Juno.

Research and development expenses. Research and development expenses were \$26.7 million for the three months ended June 30, 2020, compared to \$21.6 million for the three months ended June 30, 2019. The increase in research and development expenses was attributable primarily to the following:

- \$4.4 million increase in employee compensation and benefits expense, including \$1.9 million in employee stock-based compensation expense; and
- \$1.6 million increase in facility lease expense primarily relating to our future headquarters lease, which commenced in January 2020.

*General and administrative expenses.* General and administrative expenses were \$7.5 million for the three months ended June 30, 2020, compared to \$5.3 million for the three months ended June 30, 2019. The increase in general and administrative expenses was attributable primarily to the following:

- \$1.4 million increase in employee compensation and benefits expense, including \$1.0 million in employee stock-based compensation expense;
- \$0.3 million increase in legal, accounting and tax expenses; and
- \$0.3 million increase in facility lease expense primarily relating to our future headquarters lease, which commenced in January 2020.

Other income, net. Other income, net was \$0.6 million for the three months ended June 30, 2020 and \$0.6 million for the three months ended June 30, 2019. Other income, net for each period consisted primarily of interest income earned on cash and cash equivalents, and interest income from investments (including the amortization of discounts and premiums). Other income, net for the three months ended June 30, 2019 also included interest expense relating to the term loan with Silicon Valley Bank.

#### Comparison of the Six Months Ended June 30, 2020 and 2019

The following table summarizes the results of our operations for the six months ended June 30, 2020 and 2019 (in thousands):

	2020 2019			2019	Increase		
Collaboration revenue	\$	7,980	\$	5,449	\$	2,531	
Research and development expense		55,947		39,359		16,588	
General and administrative expense		15,232		10,620		4,612	
Total other income (expense), net		1,607		1,292		315	

*Revenue*. During the six months ended June 30, 2020, we recognized revenue of \$8.0 million under our collaboration agreements with Janssen and Ono. During the six months ended June 30, 2019, we recognized \$5.4 million under our collaboration agreements with Ono and Juno.

*Research and development expenses.* Research and development expenses were \$55.9 million for the six months ended June 30, 2020, compared to \$39.4 million for the six months ended June 30, 2019. The increase in research and development expenses was attributable primarily to the following:

- \$9.1 million increase in employee compensation and benefits expense, including \$4.0 million in employee stock-based compensation expense;
- \$6.3 million increase in clinical development and manufacturing expenses primarily relating to our product candidates derived from clonal master iPSC lines and in expenditures for laboratory equipment, materials and supplies relating to the conduct of our research activities, including under our research collaboration agreements; and
- \$3.5 million increase in facility lease expense primarily relating to our future headquarters lease, which commenced in January 2020.

These increases were partially offset by a decrease of \$3.3 million in clinical development and manufacturing expenses primarily relating to our product candidates derived from healthy donor-sourced cells.

*General and administrative expenses*. General and administrative expenses were \$15.2 million for the six months ended June 30, 2020, compared to \$10.6 million for the six months ended June 30, 2019. The increase in general and administrative expenses was attributable primarily to the following:

- \$2.8 million increase in employee compensation and benefits expense, including \$1.9 million in employee stock-based compensation expense;
- \$0.8 million increase in legal, accounting and tax expenses; and
- \$0.5 million in facility lease expense primarily relating to our future headquarters lease, which commenced in January 2020.

Other income, net. Other income, net was \$1.6 million for the six months ended June 30, 2020 and \$1.3 million for the six months ended June 30, 2019. Other income, net for each period consisted primarily of interest income earned on cash and cash equivalents, and interest income from investments (including the amortization of discounts and premiums). Other income, net for the six months ended June 30, 2019 also included interest expense relating to the term loan with Silicon Valley Bank.

#### **Liquidity and Capital Resources**

We have incurred losses and negative cash flows from operations since inception. As of June 30, 2020, we had an accumulated deficit of \$445.1 million and we anticipate that we will continue to incur net losses for the foreseeable future.

#### **Operating Activities**

During the six months ended June 30, 2020, cash provided by operating activities was \$12.2 million compared to cash used in operating activities during the six months ended June 30, 2019 of \$37.8 million. The increase was primarily attributable to cash received of \$66.0 million for the upfront fee and Equity Premium associated with the Janssen Collaboration and an increase of \$5.9 million in stock-based compensation expense. These increases were partially offset by an increase in net loss of \$18.4 million.

Agreement with Janssen Biotech, Inc.

On April 2, 2020 (the Effective Date), we entered into the Janssen Agreement with Janssen to develop iPSC-derived CAR NK and CAR T-cell product candidates for the treatment of cancer. Additionally, on the Effective Date, we entered into the Stock Purchase Agreement with JJDC. Under the terms of the Janssen Agreement and the Stock Purchase Agreement taken together, we received \$100.0 million as of the Effective Date, of which \$50.0 million is an upfront cash payment and \$50.0 million is in the form of an equity investment by JJDC. Of the \$50.0 million equity investment, \$16.0 million represented a premium over the fair value of our common stock and was classified under operating activities.

We are entitled to receive fees for the conduct of all research, preclinical development and IND-enabling activities performed by us under the Janssen Agreement. Additionally, we are eligible to receive (i) with respect to the first Janssen Cancer Target, payments of up to \$898.0 million upon the achievement of specified development, regulatory and sales milestones (the Janssen Milestone Payments) for the first Collaboration Candidate, and up to \$460.0 million in Janssen Milestone Payments for each additional Collaboration Candidate, directed to the first Janssen Cancer Target; and (ii) with respect to each of the second, third and fourth Janssen Cancer Targets, payments of up to \$706.0 million in Janssen Milestone Payments for each of the first Collaboration Candidates, and up to \$340.0 million in Janssen Milestone Payments for each additional Collaboration Candidate, directed to the applicable Janssen Cancer Target, where certain Janssen Milestone Payments are subject to reduction in the event we elect to co-commercialize and share equally in the profits and losses in the United States of a respective Collaboration Candidate. We are further eligible to receive double-digit tiered royalties ranging up to the mid-teens on net sales of Collaboration Candidates that are commercialized by Janssen under the Janssen Agreement, subject to reduction under certain circumstances. No milestone or royalty payments have been received by us as of June 30, 2020.

As a direct result of our entry into the Janssen Agreement, we incurred \$13.3 million in sublicense fees to certain of our existing licensors, of which \$4.3 million has been paid as of June 30, 2020.

Agreement with Ono Pharmaceutical Co., Ltd.

On September 14, 2018, we entered into the Ono Agreement with Ono for the joint development and commercialization of two off-the-shelf, iPSC-derived CAR T-cell product candidates (each a Candidate and collectively the Candidates). Under the terms of the Ono Agreement, Ono paid to us an upfront, non-refundable and non-creditable payment of \$10.0 million. Additionally, as consideration for our conduct of research and preclinical development under a joint development plan, Ono pays us annual research and development fees set forth in the annual budget included in the joint development plan, which fees are estimated to be \$20.0 million in aggregate over the course of the joint development plan. Further, under the terms of the Ono Agreement, Ono has agreed to pay us an additional \$40.0 million, subject to the achievement of a preclinical milestone and the exercise by Ono of its options to obtain exclusive licenses to develop and commercialize the Candidates. Such fees are in addition to the upfront payment and research and development fees.

Pursuant to the Ono Agreement, we and Ono are jointly conducting research and development activities under a joint development plan, with the goal of advancing each Candidate to a pre-defined preclinical milestone. We have granted to Ono, during a specified period of time, an option to obtain an exclusive license under certain intellectual property rights to develop and commercialize (a) Candidate 1 in Asia, with us retaining rights for development and commercialization in all other territories of the world and (b) Candidate 2 in all territories of the world, with us retaining the right to co-develop and co-commercialize Candidate 2 in the United States and Europe under a joint arrangement whereby it is eligible to share at least 50% of the profits and losses.

Subject to Ono's exercise of its options to obtain exclusive licenses to develop and commercialize the Candidates and to the achievement of certain clinical, regulatory and commercial milestones with respect to each Candidate in specified territories, we are eligible to receive an aggregate of up to \$285.0 million in milestone payments for Candidate 1 and an aggregate of up to \$895.0 million in milestone payments for Candidate 2, with the applicable milestone payments for Candidate 2 for the United States and Europe subject to reduction by 50% if we elect to co-develop and co-commercialize Candidate 2 as described above. As of June 30, 2020, we have not received any such payments. We are also eligible to receive tiered royalties ranging from the mid-single digits to the low-double digits based on annual net sales by Ono of each Candidate in specified territories, with such royalties subject to certain reductions. As of June 30, 2020, no royalties have been paid to us.

As a direct result of our entry into the Ono Agreement, we incurred an aggregate of \$2.0 million in sublicense consideration to certain of our existing licensors. The \$2.0 million in sublicense consideration represents an asset under ASC 340, *Other Assets and Deferred Costs*. As of June 30, 2020, all such consideration has been paid, with \$1.0 million paid during the six months ended June 30, 2019.

Agreement with Juno Therapeutics, Inc.

On May 4, 2015, we entered into a strategic research collaboration and license agreement with Juno Therapeutics, Inc. (the Juno Agreement) to screen for and identify small molecule modulators that enhance the therapeutic properties of Juno's genetically-engineered T-cell immunotherapies.

On May 4, 2019, the four-year initial research term under the Juno Agreement concluded as scheduled and the overall agreement terminated upon receipt of the final quarterly research payment of \$0.2 million.

#### **Investing Activities**

During the six months ended June 30, 2020, investing activities provided cash of \$59.1 million compared to cash used in investing activities of \$83.2 million during the six months ended June 30, 2019. The increase was primarily attributable to an increase in the maturities of investments of \$34.3 million and a decrease of \$106.2 million in the purchases of investments. All other investing activities for the periods presented were attributable to the purchase of property and equipment.

#### **Financing Activities**

For the six months ended June 30, 2020, financing activities provided cash of \$277.0 million, which consisted primarily of \$189.1 million of net proceeds from our June 2020 public offering of common stock, \$50.0 million of net proceeds from our June 2020 private placement of common stock, and \$33.9 million of net proceeds from the issuance of common stock in conjunction with our collaboration agreement with Janssen, which amount represents the fair value of the equity component from Janssen's common stock purchase in connection with the collaboration agreement.

For the six months ended June 30, 2019, financing activities provided cash of \$1.9 million, which consisted primarily of the issuance of common stock from equity incentive plans pursuant to the exercise of employee stock options.

From our inception through June 30, 2020, we have funded our consolidated operations primarily through the public and private sale of common stock, the private placement of preferred stock and convertible notes, commercial bank debt and revenues from collaboration activities and grants. As of June 30, 2020, we had aggregate cash and cash equivalents and investments of \$533.4 million.

#### Stock Purchase Agreement with JJDC

In April 2020, we entered into a Stock Purchase Agreement with JJDC. Under the Stock Purchase Agreement, we sold 1.6 million shares of our common stock to JJDC at \$31.00 per share, for an aggregate purchase price of \$50.0 million, of which \$34.0 million was considered an equity component of the transaction, while the remaining \$16.0 million was classified as a cash flow from operating activities.

#### Public Offering of Common Stock

In June 2020, we completed a public offering of common stock in which investors, certain of which are affiliated with one of our directors, purchased 7.1 million shares of our common stock at a price of \$28.31 per share under a shelf registration statement. Gross proceeds from the offering were \$201.3 million. After giving effect to \$12.5 million in underwriting discounts, commissions and expenses related to the offering (of which \$0.3 million was unpaid as of June 30, 2020), net proceeds were \$188.8 million.

In September 2019, we completed a public offering of common stock in which investors, certain of which are affiliated with one of our directors, purchased 9.9 million shares of our common stock at a price of \$17.50 per share under our shelf registration statement. Gross proceeds from the offering were \$173.1 million. After giving effect to \$10.7 million in underwriting discounts, commissions and expenses related to the offering, net proceeds were \$162.4 million.

#### Private Placement of Common Stock

In June 2020, we exercised our right to cause JJDC to purchase, and JJDC purchased, in a private placement 1.8 million shares of our common stock at a price of \$28.31 per share, for aggregate proceeds of \$50.0 million. The shares of common stock purchased in the private placement were not subject to any underwriting discounts or commissions.

#### California Institute for Regenerative Medicine Award

On April 5, 2018, we executed an award agreement with the CIRM pursuant to which CIRM awarded us \$4.0 million to advance our FT516 product candidate into a first-in-human clinical trial (the Award). Pursuant to the terms of the Award, we are eligible to receive five disbursements in varying amounts totaling \$4.0 million throughout the project period of the Award. In November 2019, we submitted an IND application for FT516 in advanced solid tumors. As of June 30, 2020, the Company has received aggregate disbursements under the Award in the amount of \$4.0 million.

The Award is subject to certain co-funding requirements by us. We, in our sole discretion, have the option to treat the Award either as a loan or as a grant. In the event we elect to treat the Award as a loan, we will be obligated to repay i) 60%, ii) 80%, iii) 100% or iv) 100% plus interest at 7% plus LIBOR, of the total Award to CIRM, where such repayment rate is dependent upon the phase of clinical development of FT516 at the time of our election. If we do not elect to treat the Award as a loan within 10 years of the date of the Award, the Award will be considered a grant and we will be obligated to pay to CIRM a royalty on commercial sales of FT516 until such royalty payments equal nine times the total amount awarded to us under the Award.

#### Silicon Valley Bank Debt Facility

On July 30, 2014, we entered into an Amended and Restated Loan and Security Agreement (Restated LSA) with Silicon Valley Bank (Bank), collateralized by substantially all of our assets, excluding certain intellectual property. On July 14, 2017, we entered into an amendment (SVB Loan Amendment) of the Restated LSA with the Bank where the Bank extended an additional term loan to us in the principal amount of \$15.0 million (2017 Term Loan), a portion of which was applied to repay in full all amounts previously outstanding under the Restated LSA. On November 13, 2019 we used cash on hand in the amount of \$14.2 million to repay in full all outstanding obligations related to the Restated LSA and SVB Loan Amendment. Accordingly, all of our obligations under the Restated LSA and SVB Loan Amendment have been paid and discharged in full, and all security interests and other liens granted by us to the Bank to secure our obligations have been terminated and released.

#### Registration Statements on Form S-3

In November 2018, we filed an automatic shelf registration statement (File No. 333-228513), which became effective upon filing. The shelf registration statement allows us to issue certain securities, including shares of our common stock, from time to time. The specific terms of any offering under the automatic shelf registration statement are established at the time of such offering. Additionally, we entered into a sales agreement with Leerink Partners LLC (Leerink) with respect to an at-the-market offering program, under which we may offer and sell, from time to time at our sole discretion, shares of our common stock having an aggregate offering price of up to \$50.0 million through Leerink as the sales agent, pursuant to this automatic shelf registration statement.

In addition, as of June 30, 2020, we are eligible to issue an aggregate of \$66.2 million in securities under two previously filed shelf registration statements (File Nos. 333-224680 and 333-219987), which were declared effective by the SEC in May 2018 and August 2017, respectively.

#### **Operating Capital Requirements**

We anticipate that we will continue to incur losses for the foreseeable future, and we expect the losses to increase as we continue the research, manufacture and development of, and seek regulatory approvals for, our product candidates and conduct additional research, manufacturing and development activities pursuant to our collaboration agreements with Janssen and Ono. Our product candidates have not yet achieved regulatory approval and we may not be successful in achieving commercialization of our product candidates.

We believe our existing cash and cash equivalents and investments as of June 30, 2020 will be sufficient to fund our projected operating requirements for at least the next twelve months. However, we are subject to all the risks and uncertainties incident in the research, manufacture and development of therapeutic products. For example, the FDA or other regulatory authorities may require us to generate additional data or conduct additional preclinical studies, manufacturing activities, or clinical trials, or may impose other requirements beyond those that we currently anticipate. Additionally, it is possible for a product candidate to show promising results in preclinical studies or in clinical trials, but fail to establish sufficient safety and efficacy data necessary to obtain regulatory approvals. As a result of these and other risks and uncertainties and the probability of success, the duration and the cost of our research, manufacturing and development activities required to advance a product candidate cannot be accurately estimated and are subject to considerable variation. We may encounter difficulties, complications, delays and other unknown factors and unforeseen expenses in the course of our research, manufacturing and development activities, any of which may significantly increase our capital requirements and could adversely affect our liquidity.

We will require additional capital for the research, manufacture and development of our product candidates and to perform our obligations under our collaboration agreements, and we may need to seek additional funds sooner than expected due to any changes in our business, operations, financial condition or prospects, including any impacts of the COVID-19 pandemic. We expect to finance our capital requirements in the foreseeable future through the sale of public or private equity or debt securities. However, additional capital may not be available to us on reasonable terms, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the research, manufacture or development of one or more of our product candidates. If we do raise additional funds through the issuance of additional equity or debt securities, it could result in dilution to our existing stockholders, increased fixed payment obligations and the existence of securities with rights that may be senior to those of our common stock. Additionally, if we incur indebtedness, we may become subject to financial or other covenants that could adversely restrict, impair or affect our ability to conduct our business, such as requiring us to relinquish rights to

certain of our product candidates or technologies or limiting our ability to acquire, sell or license intellectual property rights or incur additional debt. Any of these events could significantly harm our business, operations, financial condition and prospects. In addition, while the full impact of the COVID-19 pandemic on our business, operations, financial condition and prospects, and on the global economy, are currently unknown and difficult to predict, the pandemic has caused significant disruptions and created uncertainties in the global financial markets, and the economic impacts of the pandemic could materially and adversely affect our ability to raise capital through equity or debt financings in the future.

Our forecast of the period of time through which our existing cash and cash equivalents and investments will be adequate to support our operations is a forward-looking statement and involves significant risks and uncertainties. We have based this forecast on assumptions that may prove to be wrong, and actual results could vary materially from our expectations, which may adversely affect our capital resources and liquidity. We could utilize our available capital resources sooner than we currently expect. The amount and timing of future funding requirements, both near- and long-term, will depend on many factors, including, but not limited to:

- the initiation, timing, progress, size, duration, costs and results of our clinical trials and preclinical studies for our product candidates;
- the number and the nature of product candidates that we pursue;
- the time to and cost of establishing business operations at our new corporate headquarters, including internal GMP production capabilities to support the clinical and potential commercial manufacture of our product candidates;
- the cost of GMP production, process and scale-up development and technology transfer activities for the manufacture of our product candidates, including the cost of laboratory equipment, materials and supplies to support these activities;
- the time, cost and outcome of seeking and obtaining regulatory approvals;
- the extent to which we are required to pay milestone or other payments under our existing in-license agreements and any in-license agreements that we may enter into in the future, and the timing of such payments;
- the extent to which milestones are achieved under our collaboration agreements with Ono and Janssen, and any other strategic partnership or
  collaboration agreements that we may enter into in the future, and the time to achievement of such milestones and our receipt of any
  associated milestone payments;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the cost of our research and development activities, including our need and ability to hire additional employees and procure additional equipment, materials and supplies;
- the establishment and continuation of collaborations and strategic alliances;
- the timing and terms of future in-licensing and out-licensing transactions; and
- the cost of establishing sales, marketing, manufacturing and distribution capabilities for, and the pricing and reimbursement of, any products for which we may receive regulatory approval.

In addition, we are closely monitoring ongoing developments in connection with the COVID-19 pandemic and evaluating adjustments to our business and operations, which may negatively impact our financial condition and prospects and our operating results. We will continue to assess our operating capital requirements and may make adjustments to our business and operations if circumstances warrant. If we cannot continue or expand our research, manufacturing and development operations, or otherwise capitalize on our business opportunities, because we lack sufficient capital, our business, operations, financial condition and prospects could be materially adversely affected.

#### **Contractual Obligations and Commitments**

We lease certain office and laboratory space under non-cancelable operating leases. In addition to rent, our leases are subject to certain fixed fees, which have been included in the table above. The leases are also subject to additional variable charges for common area maintenance, property taxes, property insurance and other variable costs. See note 7 of the unaudited condensed consolidated financial statements for additional detail surrounding our lease obligations.

We have no material contractual obligations not fully recorded on our unaudited condensed consolidated balance sheets or fully disclosed in the notes to the financial statements.

#### **Off-Balance Sheet Arrangements**

We did not have, during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

#### Item 3. Quantitative and Qualitative Disclosures about Market Risk

#### **Interest Rate Risk**

We are exposed to market risk related to changes in interest rates. As of June 30, 2020, our cash and cash equivalents consisted of cash and money market mutual funds, and our investments consisted of United States treasuries and corporate debt securities with maturities ranging from three to eighteen months from the date of acquisition. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the low risk profile of the instruments in our portfolio, a 10% change in market interest rates would not have a material impact on our financial condition and/or results of operations.

#### **Item 4. Controls and Procedures**

#### Disclosure Controls and Procedures

We carried out an evaluation, under the supervision and with the participation of our management, including our chief executive officer, who serves as both our principal executive officer and our principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act as of the end of the period covered by this Quarterly Report on Form 10-Q. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, the individual serving as our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of June 30, 2020.

#### Changes in Internal Control over Financial Reporting

There were no changes in our internal controls over financial reporting that occurred during our latest fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting. Enhancements were made to our existing internal controls over financial reporting, effective beginning on January 1, 2020, due to the adoption and implementation of the new credit loss reporting requirements under ASU 2016-13.

#### PART II. OTHER INFORMATION

#### Item 1. Legal Proceedings

We are not a party to any material legal proceedings at this time. From time to time, we may be subject to various legal proceedings and claims that arise in the ordinary course of our business activities. Although the results of litigation and claims cannot be predicted with certainty, we do not believe we are party to any claim or litigation the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse effect on us because of defense and settlement costs, diversion of management resources and other factors.

#### Item 1A. Risk Factors

You should carefully consider the following risk factors, as well as the other information in this Quarterly Report on Form 10-Q, and in our other public filings. The occurrence of any of these risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. You should consider all of the risk factors described in our public filings when evaluating our business.

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

We are subject to risks associated with the spread of the novel coronavirus, SARS-CoV-2 (COVID-19), and the global pandemic could seriously impact the research and development of our product candidates.

The COVID-19 pandemic has broadly affected the global economy, resulted in significant travel and work restrictions in many regions and put a significant strain on healthcare resources. The pandemic has had, and we expect it will continue to have, an impact on our operations and on the operations of our collaborators, third-party contractors and other entities, including governmental agencies with which we interact. In particular, the requirement that a significant portion of our employees work remotely has had an impact on our operations and research and development of our product candidates. Additionally, we have been subject to temporary pauses in enrollment and dosing implemented by some clinical trial sites due to COVID-19, and some clinical trial sites have also restricted initiation of new trials as well as visits by sponsors and clinical research organizations (CROs) for ongoing trials to protect both site staff and patients from possible COVID-19 exposure.

The COVID-19 pandemic may in the future impact the clinical development of our product candidates if we are subject to restrictions or limitations on, or delays in, the performance of study procedures (particularly any procedures that may be deemed non-essential), participant dosing, distribution of our product candidates or clinical trial materials, study monitoring, or site inspections and data analysis, including as a result of changes in hospital or research institution policies, federal, state or local regulations, prioritization of hospital and other medical resources toward pandemic efforts, reduced availability of site staff supporting the conduct of clinical trials, heightened risks of exposure of study participants, principal investigators or site staff to COVID-19 if an outbreak occurs in their geographic region, or other reasons related to the pandemic. Quarantine or other travel limitations (whether voluntary or required) also may impede participant movement, affect access to study sites, or interrupt healthcare services.

Furthermore, the pandemic could cause delays in review and response times by the FDA and other regulatory agencies, or such health regulatory agencies may refuse to accept data from our clinical trials due to mitigation strategies we implement in response to the COVID-19 pandemic and current regulatory guidance. In addition, our ability to manufacture and ship our product candidates for our clinical trials may be impacted if we, or any third parties which manufacture and supply materials used in either the manufacture of our product candidates or the conduct of our research and development activities, or which perform certain testing relating to our product candidates, are adversely impacted by restrictions resulting from the coronavirus outbreak.

The extent to which the pandemic affects our operations and the research and development of our product candidates will depend on continuously changing circumstances, which are highly uncertain and cannot be predicted with confidence, such as the duration of the pandemic, including future waves of infection, and the actions taken to contain the pandemic or mitigate its impact. While the ultimate impact of COVID-19 on our business is highly uncertain, any negative impacts that materialize could materially adversely affect our clinical development and operations, financial performance and stock price.

#### We may face delays in initiating, conducting or completing our clinical trials, and we may not be able to initiate, conduct or complete them at all.

We are heavily dependent on our ability to complete the clinical development of, and obtain regulatory approval for, our product candidates. We have not completed the clinical trials necessary to support an application for approval to market any of our product candidates. We, or any investigators who initiate or conduct clinical trials of our product candidates, may experience delays in our current or future clinical trials, and we do not know whether we or our investigators will be able to initiate, enroll patients in, or complete, clinical trials of our product candidates on time, if at all. Current and future clinical trials of our product candidates may be delayed, unsuccessful or terminated, or not initiated at all, as a result of many factors, including factors related to:

- difficulties in identifying eligible patients for participation in clinical trials of our product candidates, due in part to our focus on the development of certain of our product candidates for the treatment of rare diseases;
- difficulties enrolling a sufficient number of suitable patients to conduct clinical trials of our product candidates, including difficulties resulting from patients enrolling in studies of therapeutic product candidates sponsored by our competitors and difficulties resulting from patient availability as a result of shelter-in-place orders, mandated travel restrictions, prioritization of hospital and other medical resources toward pandemic efforts, policies and procedures implemented at clinical sites with respect to the conduct of clinical trials, and other precautionary measures taken in treating patients or in practicing medicine in response to the COVID-19 pandemic;
- difficulties determining suitable doses of our novel cell product candidates for evaluation in clinical trials;
- difficulties in obtaining agreement from regulatory authorities on study endpoints and/or study duration, achieving study endpoints, the
  amount and sufficiency of data, demonstrating efficacy and safety, and completing data analysis in clinical trials for any of our product
  candidates:
- difficulties in obtaining agreement from regulatory authorities on the preclinical safety and efficacy data, the manufacturing requirements, and the clinical trial design and parameters necessary for an IND application to go into effect to initiate and conduct clinical trials for any of our current product candidates and any other product candidates that we may identify;
- the occurrence of unexpected safety issues or adverse events in any ongoing or future clinical trials of our product candidates, including in trials of our product candidates conducted by investigator-sponsors;
- securing and maintaining the support of clinical investigators and investigational sites, including investigators and sites who may conduct clinical trials under an investigator-sponsored IND with our financial support, and obtaining IRB approval at each site for the conduct of our clinical trials;
- governmental or regulatory delays, including any delays due to limitations on the availability of governmental and regulatory agency personnel to review regulatory filings, conduct site inspections or engage in discussions with us as a result of the COVID-19 pandemic, failure to obtain regulatory approval, or uncertainty or changes in U.S. or foreign regulatory requirements, policy or guidelines;
- limitations on clinical trial conduct at our clinical trial sites resulting from prioritization of hospital and other medical resources toward COVID-19 pandemic efforts, policies and procedures implemented at clinical sites with respect to the conduct of clinical trials including those relating to site initiation, study monitoring, and data collection and analysis, and other precautionary measures taken in treating patients or in practicing medicine in response to the COVID-19 pandemic;
- reaching agreement on acceptable terms with third-party service providers and clinical trial sites, the terms of which can be subject to
  extensive negotiation and may vary significantly among different service providers and clinical trial sites;
- failure, by us, cell processing facilities at our clinical trial sites, or third parties that we contract with, to manufacture certain of our product candidates consistently, and in sufficient quantities, in accordance with our protocol-specified manufacturing requirements and applicable regulatory requirements;
- our failure, or the failure of investigators, third-party service providers, or clinical trial sites, to ensure the proper and timely conduct of and analysis of data from clinical trials of our product candidates;
- inability to reach agreement on clinical trial design and parameters with regulatory authorities, investigators, and IRBs;
- failure or delays in obtaining sufficient quantities of suitable raw materials, components, and equipment necessary for the manufacture of any product candidate, including any inability to obtain materials as a result of possible supply chain issues related to the COVID-19 pandemic;
- challenges in distributing our product candidates to clinical trial sites, or failure to establish effective protocols for the supply and transport of our product candidates;

- the costs of conducting clinical trials or manufacturing of our product candidates being greater than we anticipate or the timelines for these activities being longer than we anticipate;
- data monitoring committees recommending suspension, termination or a clinical hold for various reasons, including concerns about patient safety;
- the serious, life-threatening diseases of the patients enrolled in our clinical trials, who may die or suffer adverse medical events during the
  course of the trials for reasons that may not be related to our product candidates;
- failure of patients to complete clinical trials or adhere to study protocols due to safety issues, side effects, disruptions in study conduct, including study monitoring, data collection and analysis, restrictions on hospital visits or travel relating to the COVID-19 pandemic, or other reasons; and
- approval of competitive agents that may materially alter the standard of care or otherwise render our product candidates or clinical trial designs obsolete.

If there are delays in initiating or conducting any clinical trials of our product candidates or any of these clinical trials are terminated before completion, the commercial prospects of our product candidates will be harmed. In addition, any delays in initiating, conducting or completing our clinical trials or adjustments to certain of our study protocols and procedures, including as a result of the COVID-19 pandemic, will increase our costs, slow down our product candidate development and regulatory approval process, and jeopardize our ability to gain regulatory approval, commence product sales and generate revenues. Furthermore, many of the factors that cause, or lead to, a delay in the initiation, conduct or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Any of these occurrences would significantly harm our business, prospects, financial condition, results of operations, and market price of shares of our common stock.

## If we fail to complete the preclinical or clinical development of, or to obtain regulatory approval for, our product candidates, our business would be significantly harmed.

All of our product candidates are currently in research or early clinical development. We have not completed clinical development of or obtained regulatory approval for any of our product candidates. Only a small percentage of research and development programs ultimately result in commercially successful products, and we cannot assure you that any of our product candidates will demonstrate the safety, purity and potency, or efficacy profiles necessary to support further preclinical study, clinical development or regulatory approval.

We may delay or cancel our ongoing research and development activities and our current or planned clinical development for any of our product candidates for a variety of reasons, including:

- determining that a product candidate is ineffective, causes harmful side effects, or otherwise presents unacceptable safety risks during preclinical studies or clinical trials;
- difficulties in manufacturing or distributing a product candidate, including the inability to manufacture and distribute a product candidate in a sufficient quantity, suitable form, or in a cost-effective manner, or under protocols and processes and with materials and facilities acceptable to the FDA for the conduct of clinical trials or for marketing approval;
- difficulty establishing predictive preclinical models for demonstration of safety and efficacy of a product candidate in one or more potential therapeutic areas for clinical development;
- the proprietary rights of third parties, which may preclude us from developing, manufacturing or commercializing a product candidate;
- determining that a product candidate may be uneconomical to develop, manufacture, or commercialize, or may fail to achieve market acceptance or an adequate pricing and reimbursement profile;
- our inability to secure or maintain relationships with strategic partners that may be necessary for advancement of a product candidate into or through clinical development, regulatory approval and commercialization in any particular indication(s) or geographic territory(ies); or
- our prioritization of other product candidates for advancement, including a decision to cease research and development of any existing product candidate due to our determination that another of our existing or future product candidates has greater potential for clinical development, regulatory approval, or commercialization, including potentially greater therapeutic benefit, a more favorable safety or efficacy profile, a more consistent or more cost effective manufacturing process, or more favorable marketing exclusivity, including greater market acceptance or commercial potential, or more advantageous intellectual property position.

Additionally, we will only be able to obtain regulatory approval to market a product candidate if we can demonstrate, to the satisfaction of the FDA or comparable foreign regulatory authorities, in well-designed and conducted clinical trials that such product candidate is manufactured in accordance with applicable regulatory requirements, is safe, pure and potent, or effective, and otherwise meets the appropriate standards required for approval for a particular indication. Our ability to obtain regulatory approval of our product candidates depends on, among other things, completion of additional preclinical studies, process development and manufacturing activities, and clinical trials, whether our clinical trials demonstrate statistically significant efficacy with safety profiles that do not potentially outweigh the therapeutic benefit, and whether regulatory agencies agree that the data from our clinical trials and our manufacturing operations are sufficient to support approval. Securing regulatory approval also requires the submission of information about product manufacturing operations to, and inspection of manufacturing facilities by, the relevant regulatory authority. The final results of our current and future clinical trials may not meet the FDA's or other regulatory agencies' requirements to approve a product candidate for marketing, and the regulatory agencies may otherwise determine that our manufacturing operations are insufficient to support approval. We may need to conduct preclinical studies and clinical trials that we currently do not anticipate. If we fail to complete preclinical or clinical development of, or obtain regulatory approval for, our product candidates, we will not be able to generate any revenues from product sales and our ability to receive milestone or other payments under any collaboration agreements may be impaired, which will harm our business, prospects, financial condition and results of operations.

The manufacture and distribution of our cell product candidates, particularly our iPSC-derived cell product candidates, is complex and subject to a multitude of risks. These risks could substantially increase our costs and limit the clinical and commercial supply of our product candidates, and the development and commercialization of our product candidates could be substantially delayed or restricted if the FDA or other regulatory authorities impose additional requirements on our manufacturing operations or if we are required to change our manufacturing operations to comply with regulatory requirements.

The manufacture and supply of our cell product candidates involve novel processes that are more complex than those required for most small molecule drugs and other cellular immunotherapies, and accordingly present significant challenges and are subject to multiple risks. For our iPSC-derived product candidates, these complex processes include reprogramming human fibroblasts to obtain iPSCs, in some cases genetically engineering these iPSCs, and differentiating the iPSCs to obtain the desired cell product candidate. As a result of the complexities in manufacturing biologics and distributing cell therapies, the cost to manufacture and distribute biologics and cell therapies in general, and our cell product candidates in particular, is generally higher than traditional small molecule chemical compounds. In addition, our cost of goods development is at an early stage. The actual cost to manufacture and process our product candidates could be greater than we expect and could materially and adversely affect the commercial viability of our product candidates.

We have limited experience in the manufacture of cell-based therapies. We are still developing optimized and reproducible manufacturing processes for clinical and commercial-scale manufacturing of our product candidates, and none of our manufacturing processes have been validated for commercial production of our product candidates. In addition, we are still optimizing our protocols for the supply and transport of our product candidates for distribution to clinical trial sites. Although we are working to develop reproducible and commercially viable manufacturing processes for our product candidates, and effective protocols for the supply and transport of our product candidates, doing so is a difficult and uncertain task.

We may make changes as we continue to develop and refine the manufacturing and distribution processes for our product candidates for advanced clinical trials and commercialization, and we cannot be sure that even minor changes in these processes will not cause our product candidates to perform differently and affect the results of our ongoing and planned clinical trials or the performance of the product once commercialized. In some circumstances, changes in our manufacturing operations, including to our protocols, processes, materials or facilities used, may require us to perform additional preclinical or comparability studies, or to collect additional clinical data from patients prior to undertaking additional clinical studies or filing for regulatory approval for a product candidate. These requirements may lead to delays in our clinical development and commercialization plans for our product candidates, and may increase our development costs substantially.

The manufacturing processes for any products that we may develop are subject to FDA and foreign regulatory authority approval requirements, and we will need to meet, and our contract manufacturing organizations (CMOs) or other third party manufacturers will need to meet, all applicable FDA and foreign regulatory authority requirements on an ongoing basis. The requirements to manufacture ProTmune in close proximity to transplant centers within a short period of time before transplantation present unprecedented complexities associated with ensuring consistent manufacture in compliance with regulatory requirements as necessary for marketing approval. Our existing product candidates are currently manufactured by us or by third-party cell processing facilities or CMOs, including facilities operated by or affiliated with our clinical sites, and we may be required to identify alternative protocols, processes, materials or facilities for the manufacture of any of these product candidates in compliance with applicable regulatory requirements. In addition, we may be required to make changes to our protocols for the supply and transport of our product candidates to enable effective distribution of our product candidates. Any modifications to our manufacturing and supply protocols, processes, materials or facilities, and any delays in, or inability to, establish acceptable manufacturing and supply operations for our product candidates could require us to incur additional development costs or result in delays to our clinical development. If we or our CMOs or other third-party manufacturers are unable to reliably produce products to specifications acceptable to the FDA or other

regulatory authorities, we may not obtain or maintain the regulatory approvals we need to commercialize such products. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or our CMOs or other third-party manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay initiation or completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations and prospects.

Our inability to manufacture sufficient quantities of our product candidates, or the loss of our third-party contract manufacturers, or our or their failure to supply sufficient quantities of our product candidates at acceptable quality levels or prices, or at all, would materially and adversely affect our business.

Developing manufacturing processes to support clinical studies and commercialization requirements is a difficult and uncertain task, and there are risks associated with scaling to the level required for clinical trials or commercialization, including, among others, cost overruns, potential problems with process scale-out, process reproducibility, stability and purity issues, lot consistency, and timely availability of acceptable reagents and raw materials. If we are unable to scale to the level required for the conduct of clinical trials or commercialization, we may not be able to produce our product candidates in a sufficient quantity to meet demand.

While certain components required for the production of our product candidates are currently manufactured internally at our facilities, we rely, and expect to continue to rely, on third parties for the manufacture of other components and also to manufacture our product candidates for use in conducting clinical trials. As such, we are required to transfer certain manufacturing process know-how and certain intermediates to third parties, including clinical cell processing facilities operated by our clinical trial sites, and larger-scale facilities operated by either a CMO, or by us, to facilitate manufacture of our product candidates for clinical trials and commercialization. Transferring manufacturing testing and processes and know-how is complex and involves review and incorporation of both documented and undocumented processes that may have evolved over time. In addition, transferring production to different facilities may require utilization of new or different processes to meet the specific requirements of a given facility. We and any CMOs or third parties that we engage for manufacturing our product candidates will need to conduct significant development work to transfer these processes and manufacture each of our product candidates for clinical trials and commercialization. In addition, we may be required to demonstrate the comparability of material generated by any CMO or third parties that we engage for manufacturing our product candidates with material previously produced and used in testing. Any inability to manufacture comparable drug product by us or our CMOs could delay the continued development of our product candidates.

In addition to relying on third parties for the manufacture of our product candidates, we also manufacture certain of our product candidates ourselves, and intend to manufacture some or all of the clinical supply of our iPSC-derived NK cell and T-cell product candidates for our ongoing and planned clinical trials. To do so, we will need to scale up our own manufacturing operations, as we do not currently have the infrastructure or capability internally to manufacture sufficient quantities of each of our product candidates to support the conduct of each of our clinical trials or commercialization of each of our product candidates, if approved. Accordingly, we will be required to make significant investments to expand our existing GMP manufacturing capabilities and facilities, establish additional GMP manufacturing facilities, conduct GMP production, and process and scale up development and technology transfer activities for the manufacture of our product candidates, and our efforts to scale our own manufacturing operations may not succeed. For example, in response to governmental shelter-in-place orders resulting from the COVID-19 pandemic, we may from time to time be required to limit our on-site staff's availability to conduct manufacturing activities at our facility, and we may encounter problems with shortages of qualified personnel, key contractors, laboratory equipment, and materials and supplies for the manufacture of our product candidates. These problems may include employee absenteeism and supply chain failures or delays relating to the COVID-19 pandemic. Further, delays in regulatory inspections, commissioning and receiving regulatory approvals for our manufacturing capabilities or facilities, including new facilities, as a result of limited governmental resources due to the COVID-19 pandemic or otherwise, could delay our development plans, including the initiation and conduct of our ongoing and planned clinical trials, and thereby limit our opportunities for growth. In addition, we and our third-part

Even if we are successful in developing manufacturing capabilities sufficient for clinical and commercial supply, problems with manufacturing operations, including difficulties with production costs and yields, quality control, stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations, could result in product defects or manufacturing failures that result in lot failures, product recalls, product liability claims or insufficient supplies of our product candidates for our ongoing and planned clinical trials or eventual commercialization. Furthermore, certain of the components currently used in manufacturing our product candidates are research-grade only, and we may encounter problems obtaining or achieving adequate quantities and quality of clinical grade materials that meet FDA, European Medicines Agency, or other applicable standards or specifications with consistent and acceptable production yields and costs. In addition, if contaminants are discovered in our supply of product candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Any such events could delay or prevent our ability to obtain regulatory approval for or commercialize our product candidates, which would adversely affect our business, prospects, financial condition and results of operations.

# Because our approach to the development of product candidates is based on novel and unproven technologies, it is subject to a substantial degree of technological uncertainty and we may not succeed in developing any of our product candidates.

All of our product candidates are currently in research, preclinical or clinical development. Only a small number of research and development programs ultimately result in commercially successful drugs. The development of cell therapies is a relatively new and emerging field, and the scientific research that forms the basis of our efforts to discover and develop programmed cellular immunotherapies is ongoing. We may determine to incorporate information learned from this research into the design of our ongoing Phase 2 clinical trial of ProTmune and our ongoing Phase 1 clinical trials of our iPSC product candidates, as well as our planned future clinical trials, which could delay or impair our clinical development activities. We may ultimately discover that our product candidates do not possess certain properties required for therapeutic effectiveness or protection from toxicity in our target patient populations. In addition, our product candidates may demonstrate different chemical and pharmacological properties in patients than they do in laboratory studies. It may take many years before we develop a full understanding of the pharmacological properties of our product candidates, and we may never know precisely how they function in vivo. As with any new biologic or product developed using novel technologies, our product candidates have an unknown immunogenicity profile. As a result, our product candidates may trigger immune responses that inhibit their therapeutic effects or cause adverse side effects. In addition, one or more of our product candidates may:

- be found ineffective or cause harmful side effects during preclinical studies or clinical trials;
- fail to receive necessary regulatory approvals on a timely basis or at all;
- be precluded from commercialization by proprietary rights of third parties;
- be difficult to manufacture on a large scale; or
- be uneconomical to commercialize or fail to achieve market acceptance.

Any such problems that affect one of our product candidates may have an unfavorable impact on all of our product candidates. As a result, we may never succeed in developing a marketable product and we may never become profitable, which would have an adverse effect on our business, prospects, financial condition, results of operations, and market price of shares of our common stock.

#### If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We are required to identify and enroll a sufficient number of patients with the disease under investigation for each of our ongoing and planned clinical trials of our product candidates, and we may not be able to identify and enroll a sufficient number of patients, or those with required or desired characteristics and who meet certain criteria, in a timely manner. In addition, we will be competing with other clinical trials of product candidates being developed by our competitors in the same therapeutic areas, and potential patients who might be eligible for enrollment in one of our clinical trials may instead choose to enroll in a trial being conducted by one of our competitors.

Our ability, and the ability of investigators, to enroll patients in our ongoing and planned clinical trials of our product candidates is affected by factors including:

- the ability to identify, solicit and recruit a sufficient number of patients;
- severity of the disease under investigation;
- design of the trial protocol;
- the relatively small size and nature of the patient populations for certain of our clinical trials;

- eligibility criteria for the trials in question;
- perceived risks and benefits of the product candidate under study, including any perceived risks associated with iPSC-derived product candidates, which we believe are the first ever iPSC-derived cell therapies cleared by the FDA for clinical investigation in the United States;
- the availability of competing therapies and clinical trials;
- efforts to facilitate timely enrollment in clinical trials;
- the availability of time and resources at the limited number of institutions at which our clinical trials are or will be conducted, including any constraints on resources, or policies and procedures implemented, at hospitals and clinical trial sites as a result of the COVID-19 pandemic;
- the availability of cells suitable for the manufacture of our clinical product candidates from eligible and qualified donors for certain of our product candidates, including ProTmune;
- the ability to monitor patients adequately during and after treatment, including through remote monitoring if required as a result of precautionary changes implemented at certain clinical trial sites as a result of the COVID-19 pandemic; and
- the proximity and availability of clinical trial sites for prospective patients.

In addition, certain of our clinical trial sites have delayed or paused patient enrollment in clinical trials as a result of the COVID-19 pandemic, and quarantines or other travel limitations relating to the COVID-19 pandemic may impede patient movement and affect access to study sites, which may further impact patient enrollment in our clinical trials. The extent and duration of such delays and disruptions, and the overall impact on the timing and conduct of our clinical trials, are uncertain. If we have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay or terminate ongoing or planned clinical trials, either of which would have an adverse effect on our business, prospects, financial condition, results of operations, and market price of shares of our common stock.

# Development of our product candidates will require substantial additional funding, without which we will be unable to complete preclinical or clinical development of, or obtain regulatory approval for, our product candidates.

We are currently advancing multiple product candidates through clinical development, and conducting preclinical research and development activities in our other programs. Drug development is expensive, and we expect our research and development expenses to increase substantially in connection with our ongoing activities, particularly as we advance our current product candidates in clinical trials and seek to initiate clinical development for additional product candidates.

As of June 30, 2020, our cash and cash equivalents and investments were \$533.4 million. We intend to use our cash and cash equivalents and investments primarily to fund the advancement and clinical development of our current product candidates and our ongoing preclinical, discovery and research programs, and for working capital and general corporate purposes. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic and licensing arrangements or a combination of these approaches. In any event, we will require additional capital to obtain regulatory approval for, and to commercialize our existing product candidates and any other product candidates we may identify and develop. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations. Our future capital requirements will depend on many factors, including, but not limited to:

- the progress, results, size, timing and costs of our ongoing and planned clinical trials, and any additional clinical trials we may initiate, conduct or support for our product candidates;
- the progress, results, size, timing and costs of our preclinical, process development and manufacturing studies, and activities necessary to
  initiate and conduct clinical trials for our product candidates and to establish and maintain manufacturing capabilities necessary to support
  such trials;
- continued progress in our research and development programs, including preclinical studies, process development, manufacturing and other research activities that may be necessary in order for an IND application to go into effect for a prospective clinical development candidate, as well as potential future clinical trials of any additional product candidates we may identify for development;
- our ability and the ability of our investigators to initiate and conduct, and the progress, results, size, timing and costs of, clinical trials of our product candidates that will be necessary to support any application for regulatory approval;

- our ability to manufacture, or enter into arrangements with third parties for the manufacture of our existing product candidates, as well as potential future clinical development candidates, both for clinical development and commercialization, and the timing and costs associated with such manufacture;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, or other costs we may incur, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- the cost of manufacturing, distribution, and commercialization activities and arrangements, including the manufacturing of our product candidates, establishment of effective protocols for the supply and transport of our product candidates, and the establishment of a sales and marketing organization either internally or in partnership with a third party; and
- our ability to establish and maintain strategic arrangements and alliances with third-party collaborators including our existing collaborations with Janssen Biotech, Inc., Ono Pharmaceutical Co., Ltd., the University of Minnesota, and Memorial Sloan Kettering, to advance the research, development and commercialization of therapeutic products.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute all of our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborative partners or otherwise at a different stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects. In addition, while the overall impact of the COVID-19 pandemic on the global economy is currently unknown and difficult to predict, the pandemic has caused significant disruptions and created uncertainties in the global financial markets, and the economic impacts of the pandemic could materially and adversely affect our ability to raise capital through equity or debt financings in the future.

If we cannot raise additional capital or obtain adequate funds, we may be required to curtail significantly our research and clinical programs or may not be able to continue our research or clinical development of our product candidates. Our failure to raise additional capital, or obtain adequate funds, will have a material adverse effect on our business, prospects, financial condition, results of operations, and market price of shares of our common stock.

The clinical development of our product candidates could be substantially delayed if we are required to conduct unanticipated studies, including preclinical studies or clinical trials, or if the FDA imposes other requirements or restrictions including on the manufacture, of our product candidates.

The FDA may require us to generate additional preclinical, product, manufacturing, or clinical data as a condition to continuing our current clinical trials, or initiating and conducting any future clinical trials of our current product candidates or other cell product candidates that we may identify. Additionally, the FDA may in the future have comments, or impose requirements, on the conduct of our clinical trials or the initiation of clinical trials or any of our other iPSC-derived cell product candidates, including the protocols, processes, materials and facilities we use to manufacture our product candidates and potential future product candidates in support of clinical trials. Any requirements to generate additional data, or redesign or modify our protocols, processes, materials or facilities, or other additional comments, requirements or impositions by the FDA, may cause delays in the initiation or conduct of the current or future clinical trials for our product candidates and subsequent development activities for our product candidates, and could require us to incur additional development or manufacturing costs and resources, seek funding for these increased costs or resources or delay our timeline for, or cease, our preclinical or clinical development activities for our product candidates, or could create uncertainty and additional complexity in our ability to obtain regulatory approval for our product candidates.

Further, if the results of our clinical trials are inconclusive, or if there are safety concerns or adverse events associated with our existing product candidates or any other product candidates we may identify, we may:

- be delayed in obtaining, or unable to obtain, regulatory approval for such product candidates;
- be required to amend the protocols for our clinical trials, perform additional nonclinical studies or clinical trials to support approval or be subject to additional post-marketing testing requirements;
- obtain approval for indications or patient populations that are not as broad as intended or desired;

- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings or contraindications; or
- in the event a product candidate is approved, have regulatory authorities withdraw their approval of the product or impose restrictions on its use.

Even if our current and planned clinical trials are successful, we will need to conduct additional clinical trials, which may include registrational trials, trials in additional patient populations or under different treatment conditions, and trials using different manufacturing protocols, processes, materials or facilities or under different manufacturing conditions, before we are able to seek approvals for our product candidates from the FDA and regulatory authorities outside the United States to market and sell these product candidates. If we fail to meet the requirements to support continued clinical development, our clinical development activities for any of our product candidates are delayed or suspended, or we fail to obtain or maintain regulatory approvals with an acceptable scope, our business, prospects, financial condition and results of operations will be harmed.

We are pursuing multiple programs and product candidates in our novel cell therapy development pipeline using an approach that is designed to enable rapid incorporation of new product features. If we elect to incorporate these new features into next-generation product candidates, this may render our existing product candidates obsolete, and we may devote our limited resources in pursuit of a particular program for which there is a greater potential for success and fail to capitalize on development opportunities or product candidates including those which may be more advanced in development.

We focus on the development of programmed cellular immunotherapies for cancer and immune disorders, including NK- and T-cell immunooncology programs that encompass off-the-shelf engineered product candidates derived from clonal master iPSC lines, and immuno-regulatory programs.
Because our iPSC product platform is designed to enable rapid incorporation of novel functional product features in an evolving clinical setting, we may
elect to incorporate these discoveries into next-generation product candidates that render our existing product candidates, including product candidates
under clinical development, obsolete. Additionally, because we have limited financial and personnel resources, we may elect or be required to abandon or
delay the pursuit of opportunities with existing or future product candidates, including those that may be more advanced in development than those we
ultimately elect to pursue. Due to these factors, our spending on current and future research and development programs and product candidates and the
scientific innovation arising from these expenditures, may not yield commercially viable product candidates.

We study our product candidates in patient populations with significant comorbidities that may result in deaths or serious adverse or unacceptable side effects and require us to abandon or limit our clinical development activities.

Patients treated with our current product candidates may also receive chemotherapy, radiation, and/or other high dose or myeloablative treatments in the course of treatment of their disease, and may therefore experience side effects or adverse events, including death, that are unrelated to our product candidates. While these side effects or adverse events may be unrelated to our product candidates, they may still affect the success of our clinical studies. The inclusion of critically ill patients in our clinical studies may result in deaths or other adverse medical events due to underlying disease or to other therapies or medications that such patients may receive. Any of these events could prevent us from advancing our product candidates through clinical development, and from obtaining regulatory approval, and would impair our ability to commercialize our product candidates. Any inability to advance our existing product candidates or any other product candidate through clinical development would have a material adverse effect on our business, and the value of our common stock would decline.

Because our product candidates are based on novel technologies, it is difficult to predict the regulatory approval process and the time, the cost and our ability to successfully initiate, conduct and complete clinical development, and obtain the necessary regulatory and reimbursement approvals, required for commercialization of our product candidates.

Our cell programming technology and platform for generating cell therapy products using iPSCs represent novel therapeutic approaches, and to our knowledge there are currently no iPSC-derived cell products approved anywhere in the world for commercial sale. As such, it is difficult to accurately predict the type and scope of challenges we may incur during development of our product candidates, and we face uncertainties associated with the preclinical and clinical development, manufacture and regulatory requirements for the initiation and conduct of clinical trials, regulatory approval, and reimbursement required for successful commercialization of these product candidates. In addition, because our iPSC-derived cell product candidates are all in the early clinical or preclinical stage, we are currently assessing safety in humans and have not yet been able to assess the long-term effects of treatment. Animal models and assays may not accurately predict the safety and efficacy of our product candidates in our target patient populations, and appropriate models and assays may not exist for demonstrating the safety and purity of our product candidates, as required by the FDA and other regulatory authorities for ongoing clinical development and regulatory approval.

The preclinical and clinical development, manufacture, and regulatory requirements for approval of novel product candidates such as ours can be more expensive and take longer than for other more well-known or extensively studied pharmaceutical or biopharmaceutical product candidates due to a lack of prior experiences on the side of both developers and regulatory agencies. Additionally, due to the uncertainties associated with the preclinical and clinical development, manufacture, and regulatory requirements for approval of our product candidates, we may be required to modify or change our preclinical and clinical development plans or our manufacturing activities and plans, or be required to meet stricter regulatory requirements for approval. Any such modifications or changes could delay or prevent our ability to develop, manufacture, obtain regulatory approval or commercialize our product candidates, which would adversely affect our business, financial condition and results of operations.

Cellular immunotherapies, and stem cell therapies and iPSC-derived cell therapies in particular, represent relatively new therapeutic areas, and the FDA has cautioned consumers about potential safety risks associated with cell therapies. To date, there are relatively few approved cell therapies. As a result, the regulatory approval process for product candidates such as ours is uncertain and may be more expensive and take longer than the approval process for product candidates based on other, better known or more extensively studied technologies and therapeutic approaches. For example, there are currently no FDA approved products with a label designation that supports the use of a product to prevent acute graft-versus-host disease in patients undergoing allogeneic hematopoietic stem cell transplantation (HSCT), which makes it difficult to determine the clinical endpoints and data required to support an application or regulatory approval, and the time and cost required to obtain regulatory approval in the United States for ProTmune.

Regulatory requirements in the United States and in other countries governing cell therapy products have changed frequently and the FDA or other regulatory bodies may change the requirements, or identify different regulatory pathways, for approval for any of our product candidates. For example, within the FDA, the Center for Biologics Evaluation and Research, or CBER, restructured and created a new Office of Tissues and Advanced Therapies to better align its oversight activities with FDA Centers for Drugs and Medical Devices. It is possible that over time new or different divisions may be established or be granted the responsibility for regulating cell and/or gene therapy products, including iPSC-derived cell products, such as ours. As a result, we may be required to change our regulatory strategy or to modify our applications for regulatory approval, which could delay and impair our ability to complete the preclinical and clinical development and manufacture of, and obtain regulatory approval for, our product candidates. Changes in regulatory authorities and advisory groups, or any new requirements or guidelines they promulgate, may lengthen the regulatory review process, require us to perform additional studies, increase our development and manufacturing costs, lead to changes in regulatory pathways, positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. As we advance our product candidates, we will be required to consult with the FDA and other regulatory authorities, and our product candidates will likely be reviewed by an FDA advisory committee. We also must comply with applicable requirements, and if we fail to do so, we may be required to delay or discontinue development of our product candidates. Delays or unexpected costs in obtaining, or the failure to obtain, the regulatory approval necessary to bring a potential product to market could impair our ability to generate sufficient product r

# Preliminary data and interim results we disclose, and results from earlier studies, may not be predictive of the final results, or of later studies or future clinical trials.

All of our product candidates are still in an early stage of development, and we cannot be assured that the development of any of our product candidates will ultimately be successful. Although we may from time to time disclose results from preclinical testing or preliminary data or interim results from clinical studies of our product candidates, such results from preclinical testing, process development and manufacturing activities, and clinical studies, including interim clinical trial results as of specified data cutoff dates and results of earlier clinical studies with similar product candidates, are not necessarily predictive of future results, including later clinical trial results. While we have demonstrated in preclinical models that a single administration of ProTmune resulted in a statistically-significant reduction in GvHD score and improvement in survival, as compared to vehicle-treated cells, we may not observe similar results in future preclinical or clinical studies of ProTmune, including our Phase 1/2 PROTECT study. Additionally, the data reported from the Phase 1 stage of PROTECT as of the November 26, 2018 data cut-off date may not continue for these subjects or be repeated or observed in ongoing or future studies involving ProTmune, including in the Phase 2 stage of the PROTECT study. It is possible that subjects for whom events of acute GvHD have been reduced or eliminated may experience acute GvHD in the future, as there is limited data concerning long-term safety and efficacy following treatment with ProTmune. Accordingly, ProTmune may not demonstrate in the Phase 2 stage of PROTECT, or in subsequent trials, an adequate safety or efficacy profile to support further development or commercialization.

The results of our current and future clinical trials may differ from results achieved in earlier preclinical and clinical studies for a variety of reasons, including:

- we may not demonstrate the potency and efficacy benefits observed in previous studies;
- our efforts to improve, standardize and automate the manufacture and supply of our product candidates and any resulting deviations in the
  manufacture of our product candidates, may adversely affect the safety, purity, potency, stability, or efficacy of such product candidates;
- differences in study design, including differences in conditioning regimens, eligibility criteria, and patient populations;
- advancements in the standard of care may affect our ability to demonstrate efficacy or achieve study endpoints in our current or future clinical trials; and
- safety issues or adverse events in patients that enroll in our current or future clinical trials.

From time to time, we also publish interim, "top-line," or preliminary data from our clinical studies. Interim data from clinical trials that we are conducting are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues, the duration of treatment increases and more patient data become available. Preliminary or "top-line" data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Material adverse changes between preliminary, "top-line," or interim data and final data could significantly harm our business prospects, financial condition and results of operations.

### Even if we obtain regulatory approval for a product candidate, our products will remain subject to regulatory scrutiny.

Any product candidate for which we obtain marketing approval, along with the manufacturing protocols, processes, materials and facilities, qualification testing, post-approval clinical data, labeling and promotional activities for such product, will be subject to continual and additional requirements of the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information, reports, registration and listing requirements, requirements relating to current cGMP, quality control, quality assurance and corresponding maintenance of records and documents, and recordkeeping. 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 conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. The FDA closely regulates the post-approval marketing and promotion of pharmaceutical and biological products to ensure such products are marketed only for the approved indications and in accordance with the provisions of the approved labeling. Later discovery of previously unknown problems with our product candidates, manufacturing operations, or failure to comply with regulatory requirements, may lead to various adverse conditions, including significant delays in bringing our product candidates to market and or being precluded from manufacturing or selling our product candidates, any of which could significantly harm our business.

We expect to rely on orphan drug status to develop and commercialize certain of our product candidates, but our existing orphan drug designations may not confer marketing exclusivity or other expected commercial benefits and we may not be able to obtain orphan drug designations for our other product candidates.

We expect to rely on orphan drug exclusivity for ProTmune and may rely on orphan drug exclusivity for other product candidates that we may develop. Orphan drug status confers seven years of marketing exclusivity in the United States under the Federal Food, Drug, and Cosmetic Act, and up to ten years of marketing exclusivity in Europe for a particular product in a specified indication, subject to certain conditions. We have been granted orphan drug designation in the United States for *ex vivo* programmed mobilized peripheral blood for the prevention of GvHD in patients undergoing allogeneic hematopoietic cell transplantation, and in the European Union for ProTmune for treatment in hematopoietic stem cell transplantation. While we have been granted these orphan designations, even if we are the first to obtain marketing approval of our product candidates for the applicable indications, we will not be able to rely on these designations to exclude other companies from manufacturing or selling biological products using the same principal molecular structural features for the same indication beyond these timeframes. Furthermore, any marketing exclusivity in Europe can be reduced from ten years to six years if the initial designation criteria have significantly changed since the market authorization of the orphan product. In addition, we may be unable to obtain orphan drug designations for any other product candidates that we are currently developing or may pursue.

For any product candidate for which we are granted orphan drug designation in a particular indication, it is possible that another company also holding orphan drug designation for the same product candidate will receive marketing approval for the same indication before we do. If that were to happen, our applications for that indication may not be approved until the competing company's period of exclusivity expires. Even if we are the first to obtain marketing authorization for an orphan drug indication in the United States, there are circumstances under which a competing product may be approved for the same indication during the seven-year period of marketing exclusivity, such as if the later product is shown to be clinically superior to our orphan product, or if the later product is deemed a different product than ours. Further, the seven-year marketing exclusivity would not prevent competitors from obtaining approval of the same product candidate as ours for indications other than those in which we have been granted orphan drug designation, or for the use of other types of products in the same indications as our orphan product.

We may be subject to certain regulations, including federal and state healthcare fraud and abuse laws and health information privacy and security laws. Any failure to comply with these regulations could have a material adverse effect on our business and financial condition.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations may be subject to various federal and state healthcare laws, including, without limitation, fraud and abuse laws, false claims laws, data privacy and security laws, as well as transparency laws regarding payments or other items of value provided to healthcare providers. These laws may impact, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. It is possible that some of our business activities could be subject to challenge under one or more of these laws. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

#### Risks Related to Our Reliance on Third Parties

We have limited experience manufacturing our product candidates on a clinical scale, and no experience manufacturing on a commercial scale. We are, and expect to continue to be, dependent on third parties to conduct some or all aspects of manufacturing of our product candidates for use in clinical trials and for commercial sale, if approved. Our business could be harmed if those third parties fail to perform satisfactorily.

We currently rely, and expect to continue to rely, on third parties, including cell processing facilities associated with clinical trial sites, to manufacture our product candidates, or certain components required for the manufacture of our product candidates, for use in conducting clinical trials and for commercial sale upon approval of any of our product candidates. In addition, we have not yet caused our product candidates to be manufactured or processed on a commercial scale and may not be able to do so for any of our product candidates.

The facilities used to manufacture our product candidates, including our own facilities, must be evaluated by the FDA or other foreign regulatory agencies pursuant to inspections that will be conducted after we submit an application to the FDA or other foreign regulatory agencies. If the FDA or a comparable foreign regulatory authority finds deficiencies with or does not approve these facilities for the manufacture of our product candidates or if it later finds deficiencies or withdraws any such approval in the future, or in the event of problems with any of the manufacturing facilities that we rely on to manufacture our product candidates or materials, we may not be able to locate additional or replacement facilities for such product candidates or materials in a timely manner and on commercially reasonable terms, or at all. This would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

Reliance on third parties for manufacture of our product candidates and components utilized in manufacturing our product candidates entails certain risks, including reliance on the third party for regulatory compliance and quality assurance, the possibility that the third-party manufacturer does not maintain the financial, personnel or other resources to meet its obligations, the possibility that the third party fails to manufacture such components, or our product candidates or any products we may eventually commercialize, in accordance with our specifications, misappropriation of our proprietary information, including our trade secrets and know-how, and the possibility of termination of our manufacturing relationship by the third party, based on its own business priorities, at a time that is costly or damaging to us. In addition, the FDA and other regulatory authorities require that our product candidates and any products that we may eventually commercialize be manufactured according to cGMP, cGTP and similar jurisdictional standards. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. The FDA or similar foreign regulatory agencies may also implement new standards at any time, or change their interpretations and enforcement of existing standards for manufacture, packaging or testing of products. We have little control over our manufacturers' compliance with these regulations and standards. In addition, the operations of our third-party manufacturers may be disrupted or delayed by the outbreak of the COVID-19 pandemic, which may impact such third-party manufacturers' ability to obtain materials for manufacture or to continue ongoing operations under shelter-in-place orders. We and our third-party manufacturers do not know yet the full extent of potential impacts on our ability to conduct our operations, including manufacture of our product candidates, and so

we and our manufacturers are continuing to monitor the situation closely. However, any failure by third parties that are manufacturing our product candidates, or components for such product candidates, to comply with cGMP or cGTP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of such components or product candidates in a timely manner, including as a result of any disruption, delay, or closure resulting from the COVID-19 pandemic, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates. In addition, such failure could be the basis for the FDA to issue a warning letter, withdraw approvals for product candidates previously granted to us, or take other regulatory or legal action, including recall or seizure of outside supplies of the product candidate, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, detention of product, refusal to permit the import or export of products, injunction or imposing civil and criminal penalties.

Our continued development of ProTmune may depend on third-party cell processing facilities for the manufacture of ProTmune under specific conditions. Any failure by these facilities to manufacture our product candidates consistently and under the proper conditions may result in delays to our clinical development plans and impair our ability to obtain approval for, or commercialize, these product candidates.

Clinical cell processing facilities operated by or affiliated with our clinical sites have manufactured ProTmune for use in our clinical trials of ProTmune to date. We will be required by the FDA to standardize the manufacture of ProTmune, and any other product candidates we may develop, including our oversight for facility and raw material and vendor qualification through to final product analytical testing and release. The manufacture of ProTmune for use in registrational clinical trials and commercialization will be subject to the requirements of applicable regulatory authorities, including the FDA, and the anticipated manufacture of these product candidates for commercialization may require each of the clinical cell processing facilities at which ProTmune is manufactured to comply with cGMP and other regulatory requirements, and be subject to inspections by the FDA or other applicable regulatory authorities that would be conducted after the submission of a biologics license application (BLA) or other marketing application. Although we are responsible for ensuring compliance with applicable regulatory requirements and for overseeing all aspects of product manufacture and release prior to applying for marketing approval, we do not control the activities of these third-party cell processing facilities and are completely dependent on their ability to comply with regulatory requirements and to properly execute the protocol for the manufacture of any of our product candidates. In particular, if the FDA requires each of the clinical cell processing facilities to comply with cGMP, there can be no guarantee that they will be able to do so. Because of these manufacturing requirements, if the applicable clinical cell processing facilities are unable to manufacture any of our product candidates, including ProTmune, in a manner that conforms to our specifications and the FDA's strict regulatory requirements, we may be required to identify alternative processes or facilities for the manufacture of such product candidate, which may require us to spend significant additional time and resources, and would impair our ability to manufacture, complete the clinical development of, and to commercialize, such product candidate. To comply with applicable regulatory and manufacturing requirements, the clinical cell processing facility may be required to possess or obtain certain equipment, including but not limited to biosafety cabinets, warming devices, cell washing devices, freezers or other materials, or to modify aspects of its operations, including its physical facility or layout, environmental systems, monitoring systems, quality systems or training procedures. If a clinical cell processing facility is unwilling or unable to comply with these regulatory or manufacturing requirements, it will be restricted or prohibited from manufacturing such product candidate and making it available for administration to patients. Any failure by these clinical cell processing facilities to properly manufacture ProTmune may adversely affect the safety and efficacy profile of such product candidate or cause the FDA or other regulatory authorities to impose restrictions or prohibitions on the manufacture and use of ProTmune in both the clinical and the commercial setting, which would have an adverse effect on our business.

We depend on strategic partnerships and collaboration arrangements, such as our collaboration arrangements with Janssen and Ono, for the development and commercialization of certain of our product candidates in certain indications or geographic territories, and if these arrangements are unsuccessful, this could result in delays and other obstacles in the development, manufacture or commercialization of any of our product candidates and materially harm our results of operations.

Our strategy for fully developing and commercializing our product candidates is dependent upon maintaining our current arrangements and establishing new arrangements with research collaborators, corporate collaborators and other third parties. We currently have corporate collaboration agreements with Janssen and Ono. These corporate collaboration agreements provide for, among other things, research funding and significant future payments should certain development, regulatory and commercial milestones be achieved. Under these arrangements, our corporate collaborators are typically responsible for:

- Electing to advance product candidates through preclinical and into clinical development;
- Conducting clinical development and obtaining required regulatory approvals for product candidates; and
- Commercializing any resulting products.

As a result, we may not be able to conduct these corporate collaborations in the manner or on the time schedule we currently contemplate, which may negatively impact our business operations.

This lack of control over the research funding for, and the development and commercialization of, certain of our product candidates could cause delays or other difficulties in the development and commercialization of any of our product candidates, which may prevent completion of research and development activities and intended regulatory filings in a timely fashion, if at all. Because we expect to continue to rely on our current corporate collaborators and to enter into new collaborations in the future, the development and commercialization of any of our product candidates could be substantially delayed, and our ability to receive future funding could be substantially impaired if one or more of our current or future collaborators:

- shifts its priorities and resources away from our collaborations due to a change in business strategies, or a merger, acquisition, sale or downsizing of its company or business unit;
- ceases development in therapeutic areas which are the subject of our collaboration;
- fails to select a product candidate for advancement into preclinical development, clinical development, or subsequent clinical development into a marketed product;
- changes the success criteria for a particular product candidate, thereby delaying or ceasing development of such product candidate;
- significantly delays the initiation or conduct of certain activities which could delay our receipt of milestone payments tied to such activities, thereby impacting our ability to fund our own activities;
- develops a product candidate that competes, either directly or indirectly, with our product candidates;
- does not obtain the requisite regulatory approval of a product candidate;
- does not successfully commercialize a product candidate;
- encounters regulatory, resource or quality issues and be unable to meet demand requirements;
- exercises its rights under the agreement to terminate the collaboration, or otherwise withdraws support for, or otherwise impairs development under the collaboration;
- disagrees on the research, development or commercialization of a product candidate resulting in a delay in milestones, royalty payments or termination of such product candidate; and
- · uses our proprietary information or intellectual property in such a way as to jeopardize our rights in such property.

In addition, the termination of the Janssen Agreement or the Ono Agreement or any future strategic partnership or collaboration arrangement that we enter into may prevent us from receiving any milestone, royalty payment, sharing of profits, and other benefits under such agreement. Furthermore, disagreements with these parties could require or result in litigation or arbitration, which would be time-consuming and expensive. Any of these events could have a material adverse effect on our ability to develop and commercialize any of our product candidates and may adversely impact our business, prospects, financial condition, and results of operations.

We currently depend on third-party cell processing facilities for the manufacture of ProTmune under specific conditions. Any failure by these facilities to manufacture our product candidates consistently and under the proper conditions may result in delays to our clinical development plans and impair our ability to obtain approval for, or commercialize, these product candidates.

Clinical cell processing facilities operated by or affiliated with our clinical sites currently manufacture ProTmune for use in our clinical trials of these product candidates. We will be required by the FDA to standardize the manufacture of ProTmune, and any other product candidates we may develop, including our oversight for facility and raw material and vendor qualification through to final product analytical testing and release. The manufacture of ProTmune for use in registrational clinical trials and commercialization will be subject to the requirements of applicable regulatory authorities, including the FDA, and the anticipated manufacture of these product candidates for commercialization may require each of the clinical cell processing facilities at which ProTmune are manufactured to comply with cGMP and other regulatory requirements, and be subject to inspections by the FDA or other applicable regulatory authorities that would be conducted after the submission of a BLA or other marketing application. Although we are responsible for ensuring compliance with applicable regulatory requirements and for overseeing all aspects of product manufacture and release prior to applying for marketing approval, we do not control the activities of these third-party cell processing facilities and are completely dependent on their ability to comply with regulatory requirements and to properly execute the protocol for the manufacture of any of our product candidates. In particular, if the FDA requires each of the clinical cell processing facilities to comply with cGMP, there can be no guarantee that they will be able to do so. Because of these manufacturing requirements, if the applicable clinical cell processing facilities are unable to manufacture any of our product candidates, including ProTmune, in a manner that conforms to our specifications and the FDA's strict regulatory requirements, we may be required to identify alternative processes or

facilities for the manufacture of such product candidate, which may require us to spend significant additional time and resources, and would impair our ability to manufacture, complete the clinical development of, and to commercialize, such product candidate. To comply with applicable regulatory and manufacturing requirements, the clinical cell processing facility may be required to possess or obtain certain equipment, including but not limited to biosafety cabinets, warming devices, cell washing devices, freezers or other materials, or to modify aspects of its operations, including its physical facility or layout, environmental systems, monitoring systems, quality systems or training procedures. If a clinical cell processing facility is unwilling or unable to comply with these regulatory or manufacturing requirements, it will be restricted or prohibited from manufacturing such product candidate and making it available for administration to patients. Any failure by these clinical cell processing facilities to properly manufacture ProTmune may adversely affect the safety and efficacy profile of such product candidate or cause the FDA or other regulatory authorities to impose restrictions or prohibitions on the manufacture and use of ProTmune in both the clinical and the commercial setting, which would have an adverse effect on our business.

Cell-based therapies depend on the availability of reagents and specialized materials and equipment which in each case are required to be acceptable to the FDA and foreign regulatory agencies, and such reagents, materials, and equipment may not be available to us on acceptable terms or at all. We rely on third-party suppliers for various components, materials and equipment required for the manufacture of our product candidates and do not have supply arrangements for certain of these components.

Manufacturing our product candidates requires many reagents and other specialty materials and equipment, some of which are manufactured or supplied by small companies with limited resources and experience to support commercial biologics production. To date, we and our clinical cell processing facilities and CMOs have purchased equipment, materials and disposables, such as automated cell washing devices, automated cell warming units, commercially available media and cell transfer and wash sets, used for the manufacture of our existing product candidates from third-party suppliers. Some of these suppliers may not have the capacity to support commercial products manufactured under cGMP by biopharmaceutical firms or may otherwise be ill-equipped to support our needs. Reagents and other key materials from these suppliers may have inconsistent attributes and introduce variability into our manufactured product candidates, which may contribute to variable patient outcomes and possible adverse events. We rely on the general commercial availability of materials required for the manufacture of our product candidates, and do not have supply contracts with many of these suppliers and may not be able to obtain supply contracts with them on acceptable terms or at all. Even if we are able to enter into such contracts, we may be limited to a sole third-party for the supply of certain required components, including our pharmacologic modulators and components for our cell processing media. As a result of the COVID-19 pandemic, the business and operations of our suppliers may be disrupted or delayed, and we in turn may experience disruptions or delays in our supply chain. An inability to continue to source product from any of these suppliers, which could be due to the impacts of the COVID-19 pandemic, regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, unexpected demands, or quality issues, could adversely affect our ability to satisfy demand for our product candidates, which could adversely and materially affect our product sales and operating results or our ability to conduct clinical trials, either of which could significantly harm our business.

If we are required to change suppliers, or modify the components, equipment, materials or disposables used for the manufacture of our product candidates, we may be required to change our manufacturing operations or clinical trial protocols or to provide additional data to regulatory authorities in order to use any alternative components, equipment, materials or disposables, any of which could set back, delay, or increase the costs required to complete our clinical development and commercialization of our product candidates. Additionally, any such change or modification may adversely affect the safety, efficacy, stability, or potency of our product candidates, and could adversely affect our clinical development of our product candidates and harm our business.

#### We face a variety of challenges and uncertainties associated with our dependence on human donor material for the manufacture of ProTmune.

ProTmune is manufactured from the blood of third-party donors, and therefore, the manufacture of ProTmune is subject to the availability and quality of the third-party donor material. The selection of the appropriate donor material for manufacture of ProTmune requires close coordination between clinical and manufacturing personnel.

ProTmune is manufactured using mobilized peripheral blood (mPB), which is currently procured directly by the clinical cell processing facilities from the National Marrow Donor Program (NMDP) for our ongoing Phase 1/2 PROTECT clinical study. The availability of mPB for the manufacture of ProTmune depends on a number of regulatory, political, economic and technical factors outside of our control, including:

- government policies relating to the regulation of mPB for clinical use;
- NMDP and individual blood bank policies and practices relating to mPB acquisition and banking;
- the pricing of mPB;

- the methods used in searching for and matching mPB to patients, which involve emerging technology related to current and future mPB
  parameters that guide the selection of an appropriate unit of mPB for transplantation; and
- methods for the procurement and shipment of mPB and its handling and storage at clinical sites.

Additionally, we do not have control over the supply, availability, price or types of mPB that these clinical cell processing facilities use in the manufacture of ProTmune. We rely heavily, and expect to continue to rely heavily, on these third parties to procure mPB that is collected in compliance with government regulations and within the current standard of care. In addition, we may identify specific characteristics of specific units of mPB, such as the volume and red blood cell content, which may limit the ability to use such units in the manufacture of ProTmune even though this mPB may otherwise be suitable for use in allogeneic transplant. As a result, the requirement for mPB to meet our specifications may limit the potential inventory of mPB eligible for use in the manufacture of ProTmune for our ongoing and any future clinical trials and for commercial supplies of ProTmune, if approved.

In the United States, the banking and use of mPB does not require a BLA, and mPB is not an FDA licensed product. However, the FDA does require that units of mPB adhere to and meet the standards set forth by the Foundation for Accreditation for Cell Therapy (FACT), the NMDP, and the American Association of Blood Banks (AABB), as applicable. In our current Phase 1/2 PROTECT clinical trial of ProTmune, ProTmune is manufactured using unlicensed mPB units. It may be possible that in the future, regulatory policy could change, and the FDA may later require that mPB units be licensed, and that ProTmune be manufactured using only licensed mPB units. Any inability to procure sufficient supplies of mPB will adversely affect our ability to develop and commercialize ProTmune.

Further, manufacture of ProTmune from donor material involves complex processes, with specialized equipment and highly skilled and trained personnel. The processes for manufacturing ProTmune are susceptible to additional risks, given the need to maintain aseptic conditions throughout the manufacturing process. Contamination with viruses or other pathogens in either the donor material or materials utilized in the manufacturing process or ingress of microbiological material at any point in the process may result in contaminated or unusable product. Such contaminations increase the risk of adverse side effects and result in delays in the development of ProTmune.

We currently rely on third parties to conduct certain research and development activities and clinical trials of our product candidates. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to timely develop, manufacture, obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We rely upon third parties, including medical institutions, clinical investigators, cell processing laboratories, and CROs for the conduct of certain research and preclinical development activities, process development and manufacturing activities, and for the conduct, management, and supervision of clinical trials of our product candidates. We do not have direct control over the activities of these third parties, and may have limited influence over their actual performance. Our reliance on these third parties and CROs does not relieve us of our responsibilities to ensure that our clinical studies are conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards.

We are responsible for complying, and we are responsible for ensuring that our third-party service providers and CROs comply, with applicable GCP for conducting activities for all of our product candidates in clinical development, including conducting our clinical trials, and recording and reporting data from these trials. Regulatory authorities enforce these regulations through periodic inspections of trial sponsors, principal investigators and trial sites. We cannot assure that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with applicable GCP requirements. In addition, our registrational clinical trials must be conducted with product produced under applicable regulatory requirements.

If these third parties and CROs do not successfully carry out their contractual duties or obligations, meet expected deadlines or successfully complete activities as planned, or if the quality or accuracy of the research, preclinical development, process development, manufacturing, or clinical data they obtain is compromised due to the failure to adhere to applicable regulatory and manufacturing requirements or for other reasons, our research, preclinical development, process development and manufacturing activities, and clinical trials, and the development of our product candidates, may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. Further, if our agreements with third parties or CROs are terminated for any reason, the development of our product candidates may be delayed or impaired, and we may be unable to advance our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

If conflicts arise between us and our collaborators or strategic partners, these parties may act in a manner adverse to us and could limit our ability to implement our strategies.

If conflicts arise between our corporate or academic collaborators or strategic partners and us, the other party may act in a manner adverse to us and could limit our ability to implement our strategies. Some of our academic collaborators and strategic partners are conducting multiple product development efforts within each area that is the subject of the collaboration with us. Our collaborators or strategic partners, however, may develop, either alone or with others, products in related fields that are competitive with the products or potential products that are the subject of these collaborations. Competing products, either developed by the collaborators or strategic partners or to which the collaborators or strategic partners have rights, may result in the withdrawal of our collaborator's or partner's support for our product candidates.

Some of our collaborators or strategic partners could also become our competitors in the future. Our collaborators or strategic partners could develop competing products, preclude us from entering into collaborations with their competitors, fail to obtain timely regulatory approvals, terminate their agreements with us prematurely, or fail to devote sufficient resources to the development and commercialization of our product candidates. Any of these developments could harm our product development efforts.

#### **Risks Related to Our Intellectual Property**

If we are unable to protect our intellectual property, or obtain and maintain patent protection for our technology and product candidates, other companies could develop products based on our discoveries, which may reduce demand for our products and harm our business.

Our commercial success will depend in part on our ability to obtain and maintain intellectual property protection for our product candidates, the operations used to manufacture them and the methods for using them, and also for our cell programming technology in order to prevent third parties from making, using, selling, offering to sell or importing our product candidates or otherwise exploiting our cell programming approach. The scope of patent protection in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are uncertain. We own and have exclusive licenses to patent portfolios for our product candidates and cell programming technology, although we cannot be certain that our existing patents and patent applications provide adequate protection or that any additional patents will issue to us with claims that provide adequate protection of our other product candidates. Further, we cannot predict the breadth of claims that may be enforced in our patents if we attempt to enforce them or if they are challenged in court or in other proceedings. If we are unable to secure and maintain protection for our product candidates and cell programming technology, or if any patents we obtain or license are deemed invalid and unenforceable, our ability to commercialize or license our technology could be adversely affected.

Others have filed, and in the future are likely to file, patent applications covering products and technologies that are similar, identical or competitive to ours or important to our business. Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that any patent application owned by a third party will not have priority over patent applications filed or in-licensed by us, or that we or our licensors will not be involved in interference, opposition, reexamination, review, reissue, post grant review or invalidity proceedings before U.S. or non-U.S. patent offices. The scope, validity or enforceability of our patents or the patents of our licensors may be challenged in such proceedings in either the courts or patent offices in the United States and abroad, and our business may be harmed if the coverage of our patents or the patents of our licensors is narrowed, or if a patent of ours or our licensors is judged invalid or unenforceable, in any such proceedings.

We depend on our licensors to prosecute and maintain patents and patent applications that are material to our business. Any failure by our licensors to effectively protect these intellectual property rights could adversely affect our business and operations.

Certain rights to our key technologies and product candidates, including intellectual property relating to ProTmune and our iPSC technology are licensed from third parties. As a licensee of third-party intellectual property, we rely on our licensors to file and prosecute patent applications and maintain patents, and otherwise protect the licensed intellectual property under some of our license agreements. We have not had and do not have primary control over these activities for certain of our licensed patents, patent applications and other intellectual property rights, and we cannot be certain that such activities will result in valid and enforceable patents and other intellectual property rights. Additionally, our licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents and we cannot be certain that our licensors will allocate sufficient resources or prioritize enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business.

## If we fail to comply with our obligations under our license agreements, we could lose rights to our product candidates or key technologies.

We have obtained rights to develop, market and sell some of our product candidates through intellectual property license agreements with third parties. These license agreements impose various diligence, milestone payment, royalty and other obligations on us. If we fail to comply with our obligations under our license agreements, we could lose some or all of our rights to develop, market and sell products covered by these licenses, and our ability to form collaborations or partnerships may be impaired. In addition, disputes may arise under our license agreements with third parties, which could prevent or impair our ability to maintain our current licensing arrangements on acceptable terms and to develop and commercialize the affected product candidates.

# We may be involved in litigation or other proceedings relating to the enforcement or defense of patent and other intellectual property rights, which could cause us to divert our resources and could put our intellectual property at risk.

If we choose to go to court to stop another party from using the inventions claimed in any patents we obtain, that individual or company has the right to ask the court to rule that such patents are invalid or should not be enforced against that third party. In addition to patent infringement lawsuits, we may be required to file interferences, oppositions, *ex parte* reexaminations, post-grant review, or *inter partes* review proceedings before the U.S. Patent and Trademark Office (the USPTO) and corresponding foreign patent offices. Litigation and other proceedings relating to intellectual property are unpredictable and expensive, and would consume time and resources and divert the attention of managerial and scientific personnel even if we were successful in any such proceeding. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for research, development, and other activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. 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. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing or misappropriating or successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

There also is a risk that a court or patent office in such proceeding will decide that our patents or the patents of our licensors are not valid or are not enforceable, and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of such patents is upheld, the court will refuse to stop the other party on the ground that such other party's activities do not infringe our rights to such patents. If we were not successful in defending our intellectual property, our competitors could develop and market products based on our discoveries, which may reduce demand for our products.

# We or our strategic partners may infringe the intellectual property rights of others, which may prevent or delay our product development efforts and stop us from commercializing, or increase the costs of commercializing, our product candidates.

Our success will depend, in part, on our ability to operate without infringing the proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, *ex part*e reexaminations, post-grant review, and *inter partes* review proceedings before the USPTO and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

We cannot guarantee that the manufacture, use or marketing of our existing product candidates or any other product candidates that we develop, or the use of our cell programming technology, will not infringe third-party patents. There may be third-party patents or patent applications with claims to materials, cell compositions, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Our competitors may have filed, and may in the future file, patent applications covering products and technologies similar to ours. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover aspects of the manufacture of any of our product candidates, any compositions formed during the manufacture, 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. Such a license may not be available on commercially reasonable terms or at all.

If a patent infringement suit were brought against us, we may be forced to stop or delay developing, manufacturing, or selling potential products that are claimed to infringe a third party's intellectual property rights, unless that third-party grants us rights to use its intellectual property. If we are unable to obtain a license or develop or obtain non-infringing technology, or if we fail to defend an infringement action successfully, or if we are found to have infringed a valid patent, we may incur substantial monetary damages, encounter significant delays in bringing our product candidates to market and be precluded from manufacturing or selling our product candidates, any of which could harm our business significantly.

#### We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed alleged trade secrets.

In conducting our business operations, we have obtained confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or other parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we could lose valuable intellectual property rights or personnel, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

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

We may be subject to claims that former employees, collaborators, or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. If we fail in defending any such claims, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. We may also be subject to monetary damages, and any of these outcomes could have a material adverse impact on our business.

# Proprietary information and invention assignment agreements with our employees and third parties may not prevent unauthorized disclosure of our trade secrets and other proprietary information.

In addition to the protection afforded by patents, we also rely upon unpatented trade secrets and improvements, proprietary know-how, and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, through confidentiality agreements with our collaborators, employees and consultants. We also have invention or patent assignment agreements with our employees and some, but not all, of our collaborators and consultants. Trade secrets, however, may be difficult to protect, and if our employees, collaborators or consultants breach these agreements, we may not have adequate remedies for any such breach, and our trade secrets may otherwise become known or independently discovered by our competitors, which would adversely affect our business position.

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

Filing, prosecuting and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with any products that we may develop and commercialize, 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, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology and pharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, 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 and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

# Changes in the patent law in the United States could diminish the value of patents in general, thereby impairing our ability to protect our product candidates and technology.

As is the case with other biotechnology companies, our success is heavily dependent on intellectual property rights, particularly patents. Obtaining and enforcing patents in the biotechnology industry involve both technological and legal complexity, and is therefore obtaining and enforcing biotechnology patents is costly, time-consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. 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. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

### The term of our patents may not be sufficient to effectively protect our market position and products.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Even if we obtain patents covering our product candidates, once the patent life has expired for a product, we may be open to competition from other products. If the lives of our patents are not sufficient to effectively protect our products and business, our business and results of operations will be adversely affected.

#### **Risks Related to the Commercialization of Our Product Candidates**

We do not have experience marketing any product candidates and do not have a sales force or distribution capabilities, and if our products are approved we may be unable to commercialize them successfully.

We currently have no experience in marketing and selling therapeutic products. If any of our product candidates are approved for marketing, we intend to establish marketing and sales capabilities internally or we may selectively seek to enter into partnerships with other entities to utilize their marketing and distribution capabilities. If we are unable to develop adequate marketing and sales capabilities on our own or effectively partner with third parties, our ability to generate product revenues will suffer.

# The commercial success of our product candidates will depend upon the degree of market acceptance by physicians, patients, third-party payers and others in the medical community.

The commercial success of our products, if approved for marketing, will depend in part on the medical community, patients and third-party payers accepting our product candidates as effective and safe. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of our products, if approved for marketing, will depend on a number of factors, including:

- the safety and efficacy of the products, and advantages over alternative treatments;
- the labeling of any approved product;
- the prevalence and severity of any side effects, including any limitations or warnings contained in a product's approved labeling;
- the emergence, and timing of market introduction, of competitive products;
- · the effectiveness of our marketing strategy; and
- sufficient third-party insurance coverage or governmental reimbursement, which may depend on our ability to provide compelling evidence that a product meaningfully improves health outcomes to support such insurance coverage or reimbursement.

Even if a potential product displays a favorable efficacy and safety profile in preclinical studies and clinical trials, market acceptance of the product will not be known until after it is launched. Any failure to achieve market acceptance for our product candidates will harm our business, results and financial condition.

We expect to face uncertainty regarding the pricing of our existing product candidates and any other product candidates that we may develop. If pricing policies for our product candidates are unfavorable, our commercial success will be impaired.

Due to the novel nature of our product candidates, and the targeted indication of HSCT procedures in general and our cellular immunotherapy product candidates in particular, we face significant uncertainty as to the pricing of any such products for which we may receive marketing approval. While we anticipate that pricing for any cellular immunotherapy product candidates that we develop will be relatively high due to their anticipated use in the prevention or treatment of life-threatening diseases where therapeutic options are limited, the biopharmaceutical industry has recently experienced significant pricing pressures, including in the area of orphan drug products. In particular, drug pricing and other healthcare costs continue to be subject to intense political and societal pressures, which we anticipate will continue and escalate on a global basis. These pressures may result in harm to our business and reputation, cause our stock price to decline or experience periods of volatility and adversely affect results of operations and our ability to raise funds.

# The insurance coverage and reimbursement status of newly-approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for new products could limit our product revenues.

Our ability to commercialize any of our product candidates successfully will depend in part on the extent to which reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers, and other organizations. The availability and extent of reimbursement by governmental and private payers is essential for most patients to be able to afford expensive treatments, such as HSCT or cellular immunotherapy. There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products by government and third-party payers. In particular, there is no body of established practices and precedents for reimbursement of cellular immunotherapies, and it is difficult to predict what the regulatory authority or private payer will decide with respect to reimbursement levels for novel products such as ours. Our products may not qualify for coverage or direct reimbursement, or may be subject to limited reimbursement. If reimbursement or insurance coverage is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be sufficient to allow us to establish or maintain pricing to generate income.

In addition, reimbursement agencies in foreign jurisdictions may be more conservative than those in the United States. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits. Moreover, increasing efforts by governmental and third-party payers, in the United States and abroad, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. Failure to obtain or maintain adequate reimbursement for any products for which we receive marketing approval will adversely affect our ability to achieve commercial success, and could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products, and our overall financial condition.

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

We focus our research and development on product candidates for orphan indications and other 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 estimates. These estimates may prove to be incorrect, and new studies may change the estimated incidence or prevalence of these diseases. The number of patients in the United States, Europe and elsewhere may turn out to be lower than expected or may not be otherwise amenable to treatment with our products, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business. Additionally, because our target patient populations are small, we will be required to capture a significant market share to achieve and maintain profitability.

## Healthcare legislative or regulatory reform measures may have a negative impact on our business and results of operations.

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, the Affordable Care Act (ACA) was passed, which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. Since its enactment, there have been many judicial, President, and Congressional challenges to numerous aspects of the ACA. As a result, the full impact on our business of the ACA, the potential impacts of any challenges including any laws repealing and/or replacing elements of it, as well as the political uncertainty surrounding any repeal or replacement legislation, remain unclear.

Additionally, at the federal level, statutes and regulations routinely impact a variety of parameters relating to federal programs and Medicare. In July 2018, the Centers for Medicare and Medicaid Services (CMS) published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. The full impact of these federal and state laws and regulations, as well as other new laws and reform measures that may be proposed and adopted in the future, remains uncertain, but may result in additional reductions in Medicare and other healthcare funding, which could have an adverse effect on customers for our product candidates, if approved, and, accordingly, our financial operations.

Additionally, there has been heightened governmental scrutiny in the United States of pharmaceutical and biologics pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in various congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products.

We expect that these and 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 approved drug. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drugs.

In addition, FDA regulations and guidance may be revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. The Trump administration has also taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these requirements will be interpreted and implemented and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose restrictions on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. Any new regulations or guidance, or revisions or reinterpretations of existing regulations or guidance, may impose additional costs or lengthen FDA review times for our existing product candidates or any future product candidates we may develop. We cannot determine how changes in regulations, statutes, policies, or interpretations when and if issued, enacted or adopted, may affect our business in the future. Such changes could, among other things, require:

- additional non-clinical or clinical trials to be conducted prior to obtaining approval;
- changes to manufacturing methods;
- recalls, replacements, or discontinuance of one or more of our products; and
- additional recordkeeping.

Such changes would likely require substantial time and impose significant costs, or could reduce the potential commercial value of our existing product candidates or other product candidates we may develop, and could materially harm our business and our financial results. In addition, delays in receipt of or failure to receive regulatory clearances or approvals for any other products would harm our business, prospects, financial condition, and results of operations.

### Risks Related to Our Business and Industry

The success of our existing product candidates is substantially dependent on developments within the field of HSCT and cellular immunotherapy, some of which are beyond our control.

Our product candidates are designed and are being developed as therapeutic entities for use as cellular immunotherapies. Any adverse developments in the field of cellular immunotherapy generally, and in the practice of HSCT in particular, will negatively affect our ability to develop and commercialize our product candidates. If the market for HSCT procedures declines or fails to grow at anticipated levels for any reason, or if the need for patients to undergo HSCT procedures is obviated due to the development and commercialization of therapeutics targeting the underlying cause of diseases addressed by HSCT, our business prospects will be significantly harmed.

#### We face competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We face competition from biotechnology and pharmaceutical companies, universities, and other research institutions, and many of our competitors have greater financial and other resources, such as larger research and development staff and more experienced marketing and manufacturing organizations and facilities. In particular, there are several companies and institutions developing products that may obviate the need for HSCT, may be competitive to our iPSC-derived product candidates or candidates in our research and development pipeline, or may render our product candidates obsolete or noncompetitive. Should one or more of these products be successful, the market for our products may be reduced or eliminated, and we may not achieve commercial success.

### We may not be able to manage our business effectively if we are unable to attract and retain key personnel and consultants.

We may not be able to retain or attract qualified management, finance, scientific and clinical personnel and consultants due to the intense competition for qualified personnel and consultants among biotechnology, pharmaceutical and other businesses. If we are not able to retain and attract necessary personnel and consultants to perform the requisite operational roles and accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

#### The global COVID-19 pandemic could adversely impact various aspects of our business, results of operations and financial condition.

As a result of the COVID-19 pandemic, various aspects of our business operations have been, and could continue to be, disrupted. In response to the pandemic, we have implemented a work from home policy, with our administrative employees continuing their work outside of our offices, and imposed onsite occupancy limits, restricting on-site staff to only those required to execute certain laboratory, manufacturing and related support activities, and requiring self-health testing prior to coming onsite. The increase in working remotely could increase our cybersecurity risk, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business operations or delay necessary interactions with local and federal regulators, ethics committees, manufacturing sites, and clinical trial sites. In addition, as a result of shelter-in-place orders or other mandated travel restrictions, our on-site staff conducting research and development, preclinical studies, and manufacturing activities may not be able to access our laboratories or manufacturing space, and these core activities may be significantly limited or curtailed, possibly for an extended period of time, which could impair our ability to complete IND-enabling studies or select future development candidates. Our business operations may be further disrupted if any of our employees, officers or directors, or their respective personal or business contacts, contract an illness related to COVID-19 and render them unable to perform their duties as a result.

In addition, the trading prices for our common stock and other biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through equity or debt financings, or such financing transactions may be on unfavorable terms. While the potential economic impact brought by and the duration of the pandemic may be difficult to assess or predict, it has already caused, and is likely to result in further, significant disruptions and uncertainties in global financial markets, which may reduce our ability to access capital either at all or on favorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the spread of COVID-19 could materially and adversely affect our business and the value of our common stock.

The ultimate impact of the current pandemic, or any other health epidemic, is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical and preclinical programs, our clinical, preclinical, research, manufacturing, and regulatory activities, healthcare systems or the global economy as a whole. However, these effects could have a material adverse impact on our operations, and we will continue to monitor the situation closely.

# If we fail to maintain an effective system of disclosure controls and procedures and internal controls, our ability to produce accurate financial statements or comply with applicable regulations could be impaired.

As a public company, we are required to comply with the Sarbanes-Oxley Act of 2002, as amended (the Sarbanes-Oxley Act), and the related rules and regulations of the SEC, expanded disclosure requirements, accelerated reporting requirements and more complex accounting rules. Company responsibilities required by the Sarbanes-Oxley Act include establishing and maintaining corporate oversight and adequate internal control over financial reporting and disclosure controls and procedures. Effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent financial fraud.

We cannot assure that we will not have material weaknesses or significant deficiencies in our internal control over financial reporting. If we are unable to successfully remediate any material weakness or significant deficiency in our internal control over financial reporting, or identify any material weaknesses or significant deficiencies that may exist, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, and our stock price may decline materially as a result.

# If we engage in an acquisition, reorganization or business combination, we will incur a variety of risks that could adversely affect our business operations or our stockholders.

From time to time, we have considered, and we will consider in the future, strategic business initiatives intended to further the expansion and development of our business. These initiatives may include acquiring businesses, technologies or products or entering into business combinations with other companies. If we pursue such a strategy, we could, among other things:

- issue equity securities that would dilute our current stockholders' percentage ownership;
- incur substantial debt that may place strains on our operations;
- spend substantial operational, financial and management resources to integrate new businesses, technologies and products;
- assume substantial actual or contingent liabilities;
- reprioritize our development programs and even cease development and commercialization of our product candidates; or
- merge with, or otherwise enter into a business combination with, another company in which our stockholders would receive cash or shares of the other company on terms that certain of our stockholders may not deem desirable.

Although we intend to evaluate and consider acquisitions, reorganizations and business combinations in the future, we have no agreements or understandings with respect to any acquisition, reorganization or business combination at this time.

### We face potential product liability exposure far in excess of our limited insurance coverage.

The use of our product candidates in clinical trials, and the sale of any products for which we obtain marketing approval, exposes us to the risk of product liability claims. Product liability claims might be brought against us by participants in clinical trials, hospitals, medical centers, healthcare providers, pharmaceutical companies, and consumers, or by others selling, manufacturing or otherwise coming into contact with our product candidates. We carry product liability insurance and we believe our product liability insurance coverage is sufficient in light of our current clinical programs. In addition, if and when we obtain marketing approval for product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain insurance coverage for any approved products on commercially reasonable terms or in sufficient amounts to protect us against losses due to liability.

On occasion, large judgments have been awarded in class action lawsuits based on drugs or medical treatments that had unanticipated adverse effects. In addition, under some of our agreements with clinical trial sites, we are required to indemnify the sites and their personnel against product liability and other claims. A successful product liability claim, or a series of claims, brought against us or any third parties whom we are required to indemnify could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

Patients with the diseases targeted by our product candidates are often already in severe and advanced stages of disease and have both known and unknown significant pre-existing and potentially life-threatening health risks. During the course of treatment, patients may suffer adverse events, including death, for a variety of reasons. Such events, whether or not resulting from our product candidates, could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively affect or end our opportunity to receive or maintain regulatory approval to market our products, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which we do not believe that an adverse event is related to our products, the investigation into the circumstance may be time-consuming or inconclusive. These investigations may interrupt our development and commercialization efforts, delay our regulatory approval process, or impact and limit the type of regulatory approvals our product candidates receive or maintain. As a result of these factors, a product liability claim, even if successfully defended, could have a material adverse effect on our business, financial condition or results of operations.

If we fail to comply with environmental, health, and safety laws and regulations, including regulations governing the handling, storage or disposal of hazardous materials, we could become subject to fines or penalties or incur costs that could harm our business.

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

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

# Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with the regulations of the FDA or foreign regulators, to provide accurate information to the FDA or foreign regulators, to comply with healthcare fraud and abuse laws and regulations in the United States and abroad, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. Employee and independent contractor misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. If any actions alleging such conduct are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant effect on our business, including the imposition of significant fines or other sanctions.

Our business activities may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, physician payment transparency laws, health information privacy and security laws, and anti-bribery and anti-corruption laws. Our actual or perceived failure to comply with such laws or their relevant foreign counterparts could adversely affect our business.

Our business activities may be subject to the Foreign Corrupt Practices Act (FCPA) and various federal and state fraud and abuse laws, including, without limitation, physician sunshine laws and regulations, and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits improper payments or offers of payments, either directly or indirectly, to foreign governments and their officials and political parties by U.S. persons in order to influence official action, or otherwise obtain or retain business. Additionally, the U.S. federal physician payment transparency requirements, sometimes referred to as the "Physician Payments Sunshine Act," created under the Affordable Care Act, and their implementing regulations, require manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the Centers for Medicare and Medicaid Services, information related to payments or other transfers of value made to physicians, other healthcare providers, and teaching hospitals, as well as ownership and investment interests held by physicians, other healthcare providers, and their immediate family members. The federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) imposes criminal and civil liability for knowingly and willfully defrauding any healthcare benefit program or knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services.

We and any potential collaborators may be subject to federal, state, and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA, as amended by Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH). Depending on the facts and circumstances, we could be subject to civil, criminal, and administrative penalties if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. There is no certainty that all of our employees, agents, suppliers, manufacturers, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws.

In addition, as of May 25, 2018, the General Data Protection Regulation (GDPR) regulates the collection and use of personal data in the EU. The GDPR covers any business, regardless of its location, that provides goods or services to residents in the EU and, thus, could incorporate our activities in EU member states. The GDPR imposes strict requirements on controllers and processors of personal data, including special protections for "sensitive information," which includes health and genetic information of individuals residing in the EU. GDPR grants individuals the opportunity to object to the processing of their personal information, allows them to request deletion of personal information in certain circumstances, and provides the individual with an express right to seek legal remedies in the event the individual believes his or her rights have been violated. Further, the GDPR imposes strict rules on the transfer of personal data out of the EU to regions that have not been deemed to offer "adequate" privacy protections, such as the U.S. currently. Failure to comply with the requirements of the GDPR and the related national data protection laws of the EU member states, which may deviate slightly from the GDPR, may result in warning letters, mandatory audits and financial penalties, including fines of up to 4% of global revenues, or €20,000,000, whichever is greater. As a result of the implementation of the GDPR, we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules.

There is significant uncertainty related to the manner in which data protection authorities will seek to enforce compliance with GDPR. For example, it is unclear whether the authorities will conduct random audits of companies doing business in the EU, or act solely after complaints are filed claiming a violation of the GDPR. The lack of compliance standards and precedent, enforcement uncertainty and the costs associated with ensuring GDPR compliance may be onerous and adversely affect our business, financial condition, results of operations and prospects.

Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of facilities, including those of our suppliers and manufacturers, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries as well as difficulties in manufacturing or continuing to develop our products, and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition.

We or the third parties upon whom we depend may be adversely affected by earthquakes or other natural disasters, including epidemics and pandemics such as COVID-19, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Earthquakes or other natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our manufacturing facilities or those of our CMOs, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. For example, as a result of the COVID-19 pandemic, we may experience delays or disruptions in our clinical development activities, our research and development activities, and in the supply of drug product for our clinical trials. Any continued or subsequent measures taken by governmental authorities or businesses to contain the spread of COVID-19, or the perception that such measures may be required in the future should another outbreak occur, could adversely affect our business, operations, financial condition, prospects or results of operations by restricting our ability to conduct our clinical trials and research and development activities, and limiting our and our third-party manufacturers' ability to manufacture product and forcing temporary closure of our facilities and facilities that we rely upon. The disaster recovery and business continuity plans we have in place currently are limited and may not prove adequate for protecting and continuing our business in the event that our business is disrupted as a result of the COVID-19 pandemic or other serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

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

Our ability to invest in and expand our business and meet our financial obligations, to attract and retain third-party contractors and collaboration partners and to raise additional capital depends on our operating and financial performance, which, in turn, is subject to numerous factors, including the prevailing economic and political conditions and financial, business, regulatory and other factors beyond our control, such as the rate of unemployment, the number of uninsured persons in the United States, political influences and inflationary pressures. For example, an overall decrease in or loss of insurance coverage among individuals in the United States due to high levels of unemployment (particularly as a result of the COVID-19 pandemic), underemployment or the repeal of certain provisions of the PPACA may decrease the demand for healthcare services and pharmaceuticals. Additionally, the availability of healthcare services and resources is currently constrained due to the COVID-19 pandemic. If fewer patients are seeking medical care because they do not have insurance coverage or are unable to obtain medical care for their conditions due to resource constraints on the healthcare system, we may experience difficulties in any eventual commercialization of our product candidates and our business, results of operations, financial condition and cash flows could be adversely affected.

In addition, our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets upon which pharmaceutical and biopharmaceutical companies such as us are dependent for sources of capital. In the past, global financial crises have caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, including as a result of the COVID-19 pandemic, could result in a variety of risks to our business, including a reduced ability to raise additional capital when needed on acceptable terms, if at all, and weakened demand for our product candidates. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the COVID-19 pandemic, current economic climate and financial market conditions could adversely impact our business.

# Our internal computer systems, or those used by our third-party research institution collaborators, CROs or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our future CROs and other contractors, vendors, and consultants may be vulnerable to damage from computer viruses and unauthorized access. In addition, these vulnerabilities may be heightened as a result of remote work policies implemented by us and our third-party contractors in response to the COVID-19 pandemic. We have from time to time experienced, and may continue to experience in the future, cyber-attacks on our information technology systems despite our best efforts to prevent them. Although such breaches have been immaterial to our business to date, investigations into and remedial efforts in connection with any breaches, even those with immaterial impact, can be costly and time-consuming, and any future breaches could be material, or cause significant disruption, to our business. For example, the loss of clinical trial data from completed, ongoing or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for research and development, the manufacture and supply of drug product and drug substance and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed.

Certain data breaches must also be reported to affected individuals and the government, and in some cases to the media, under provisions of HIPAA, as amended by HITECH, other U.S. federal and state law, and requirements of non-U.S. jurisdictions, including the European Union Data Protection Directive, and financial penalties may also apply.

Our insurance policies may not be adequate to compensate us for the potential losses arising from breaches, failures or disruptions of our infrastructure, catastrophic events and disasters or otherwise. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and defending a suit, regardless of its merit, could be costly and divert management's attention.

Furthermore, 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.

## Risks Related to Our Financial Condition and the Ownership of Our Common Stock

We have a limited operating history, have incurred significant losses since our inception, and anticipate that we will continue to incur significant losses for the foreseeable future.

We are a clinical-stage biopharmaceutical company formed in 2007 with a limited operating history. We have not yet obtained regulatory approval for any of our product candidates or generated any revenues from therapeutic product sales. Since inception, we have incurred significant net losses in each year and, as of June 30, 2020, we had an accumulated deficit of \$445.1 million. We expect to continue to incur losses for the foreseeable future as we continue to fund our ongoing and planned clinical trials of our product candidates, and our other ongoing and planned research and development activities. We also expect to incur significant operating and capital expenditures as we continue our research and development of, and seek regulatory approval for, our product candidates, in-license or acquire new product candidates for development, implement additional infrastructure and internal systems, and hire additional scientific, clinical, and administrative personnel. We anticipate that our net losses for the next several years could be significant as we conduct our planned operations.

Because of the numerous risks and uncertainties associated with pharmaceutical, biological, and cell therapy 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. In addition, our expenses could increase if we are required by the FDA, or comparable foreign regulatory authorities, to perform studies or trials in addition to those currently expected, or if there are any delays in completing our clinical trials, preclinical studies, process development, manufacturing activities, or the research and development of any of our product candidates. The amount of our future net losses will depend, in part, on the rate of increase in our expenses, our ability to generate revenues and our ability to raise additional capital. These net losses have had, and will continue to have, an adverse effect on our stockholders' equity and working capital.

#### Our stock price is subject to fluctuation based on a variety of factors.

The market price of shares of our common stock could be subject to wide fluctuations as a result of many risks listed in this section, and other risks beyond our control, including:

- the timing of the initiation of, and progress in, our current and planned clinical trials;
- the results of our clinical trials and preclinical studies, and the results of clinical trials and preclinical studies by others for product candidates or indications similar to ours:
- developments related to the FDA or to regulations applicable to cellular immunotherapies generally or our product candidates in particular including, but not limited to, regulatory pathways and clinical trial requirements for approvals;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments:
- communents;
- additions or departures of key management or scientific personnel;
- actual or anticipated changes in our research and development activities and our business prospects, including in relation to our competitors;

developments related to proprietary rights including patents, litigation matters and our ability to obtain patent protection for our technologies;

- developments of technological innovations or new therapeutic products by us or others in the field of immunotherapy;
- announcements or expectations of additional equity or debt financing efforts;
- sales of our common stock by us, including pursuant to the terms of our stock purchase agreement with Juno Therapeutics, Inc., or by our insiders or our other stockholders;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- comments by securities analysts;
- · fluctuations in our operating results; and
- general economic and market conditions.

These and other market and industry factors, including the effects of the COVID-19 pandemic on the global economy, may cause the market price and demand for our common stock to fluctuate substantially regardless of our actual operating performance, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock. In addition, the stock market in general, and the Nasdaq Global Market and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit and this could divert the time and attention of our management.

# Our principal stockholders and management own a significant percentage of our stock and may be able to exercise significant control over our company.

As of August 3, 2020, our executive officers, directors and entities affiliated with our five percent stockholders beneficially own, in the aggregate, shares representing approximately 38.3% of our outstanding voting stock. If, in accordance with the CoD (as such term is defined in Note 8 of the notes to the consolidated financial statements herewith) relating to the Class A Convertible Preferred Stock, Redmile (as such term is defined in Note 8 of the notes to the consolidated financial statements herewith) elects to remove certain limitations on the percentage of the our outstanding common stock that it may own such that the 2,794,549 shares of Class A Convertible Preferred Stock currently held by Redmile become fully convertible at Redmile's option into 13,972,745 shares of common stock, the beneficial ownership of our executive officers, directors and entities affiliated with our five percent stockholders would increase to 46.5%. Although we are not aware of any voting arrangements in place among these stockholders, if these stockholders were to choose to act together, as a result of their stock ownership, they would be able to influence our management and affairs and control all matters submitted to our stockholders for approval, including the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of ownership may have the effect of delaying or preventing a change in control of our company that our other stockholders may believe are in their best interests, or adversely affecting the liquidity, volatility, and market price of our common stock. For example, if any of our directors, executive officers or other entities affiliated with our five percent stockholders elect to sell, transfer or otherwise dispose of a significant amount of shares of our common stock, this could result in a decrease in our stock price. Furthermore, any transferees or successors of all or a significant portion of our existing stockholders' ownership in u

# We may sell additional equity or debt securities or enter into other arrangements to fund our operations, which may result in dilution to our stockholders and impose restrictions or limitations on our business.

We expect that significant additional capital will be needed in the future to continue our planned operations, and we may seek additional funding through a combination of equity offerings, debt financings, state or government grants, strategic alliances, licensing and collaboration arrangements, or other third-party business arrangements. These financing activities may have an adverse effect on our stockholders' rights, the market price of our common stock and on our operations and may require us to relinquish rights to some of our technologies, intellectual property or product candidates, issue additional equity or debt securities, or otherwise agree to terms unfavorable to us. For example, we registered all of the 5,250,000 shares of common stock issued by us in our August 2016 private placement transaction for resale on a Form S-3, which was declared effective by the SEC in September 2016. We also registered all of the 6,766,915 shares of common stock issued by us and all 14,097,745 shares of common stock issuable upon the conversion of an aggregate of 2,819,549 shares of Class A Convertible Preferred Stock issued by us in our November 2016 private placement transaction for resale on a Form S-3, which was declared effective by the SEC in January 2017. As a result, all of these shares are currently available for resale to the public, which may result in dilution to our stockholders. During 2019, 25,000 shares of the Class A Convertible Preferred Stock were converted into 125,000 shares of common stock. In addition, pursuant to a shelf registration statement declared effective by the SEC in May 2018, we may sell up to a remaining \$6.2 million in shares of our common stock, preferred stock, debt securities, warrants and/or units, and pursuant to a shelf registration statement declared effective by the SEC in August 2017, we may sell up to a remaining \$54.0 million in the aggregate of shares of our common stock, preferred stock, debt securities, warrants and/or units. The August 2017 registration statement also provides for the resale by Juno of up to one million shares of common stock held by Juno pursuant to the Stock Purchase Agreement entered into in May 2015. Further, in November 2018 we filed a Form S-3 pursuant to which we may issue up to \$50.0 million in common stock in sales deemed to be an "at the market offering" as defined by the Securities Act of 1933, as amended (the Securities Act) and, so long as we qualify as a "well-known seasoned issuer" as defined in Rule 405 of the Securities Act, an unlimited amount of shares of our common stock, preferred stock, debt securities, warrants and/or units. Additionally, we have agreed to register the shares of common stock issued to Johnson & Johnson Innovation – JJDC, Inc. under a stock purchase agreement entered into in connection with the Janssen Agreement pursuant to a registration statement on Form S-3. Any sale or issuance of securities pursuant to a registration statement or otherwise may result in dilution to our stockholders and may cause the market price of our stock to decline, and new investors could gain rights superior to our existing stockholders. In addition, any debt financings that we may enter into in the future may impose restrictive covenants or otherwise adversely affect the holdings or the rights of our stockholders, and any additional equity financings will be dilutive to our stockholders. Furthermore, additional equity or debt financing might not be available to us on reasonable terms, if at all.

#### We have broad discretion over the use of our cash, cash equivalents, and investments and may not use them effectively.

Our management has broad discretion to use our cash, cash equivalents, investments and any additional funds that we may raise to fund our operations and could spend these funds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline or delay the development of our product candidates. We may invest our cash and cash equivalents in a manner that does not produce income or that loses value.

# Provisions of Delaware law or our charter documents could delay or prevent an acquisition of our company, and could make it more difficult for you to change management.

Provisions of Delaware law, our amended and restated certificate of incorporation, and our amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions may also prevent or delay attempts by stockholders to replace or remove our current management or members of our board of directors. These provisions include:

- a classified board of directors with limitations on the removal of directors;
- advance notice requirements for stockholder proposals and nominations;
- the inability of stockholders to act by written consent or to call special meetings;
- the ability of our board of directors to make, alter or repeal our amended and restated bylaws; and
- the authority of our board of directors to issue preferred stock with such terms as our board of directors may determine.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge or combine with us. Any provision of our amended and restated certificate of incorporation or amended and restated bylaws or Delaware law that has the effect of delaying or discouraging a potential acquisition proposal or tender offer could limit the opportunity for our stockholders to achieve liquidity for their shares of our common stock, even if the acquisition proposal or tender offer is at a premium over the then-current market price for our common stock, and could also affect the price that some investors are willing to pay for our common stock.

#### Changes in tax law may adversely affect us or our investors.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service, or IRS, and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. For example, the Tax Cuts and Jobs Act, or the TCJA, was enacted in 2017 and made significant changes to corporate taxation, including the reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, the limitation of the tax deduction for net interest expense to 30% of adjusted taxable income (except for certain small businesses), the limitation of the deduction for net operating losses to 80% of current year taxable income and the elimination of net operating loss carrybacks (though any such net operating losses may be carried forward indefinitely), and the modification or repeal of many business deductions and credits. Additionally, on March 27, 2020, President Trump signed into law the Coronavirus Aid, Relief, and Economic Security Act, which, among other things, suspends the 80% limitation on the deduction for net operating losses in taxable years beginning before January 1, 2021, permits a 5-year carryback of net operating losses arising in taxable years beginning after December 31, 2017 and before January 1, 2021, and generally caps the limitation on the deduction for net interest expense at 50% of adjusted taxable income for taxable years beginning in 2019 and 2020. It cannot be predicted whether, when, in what form, or with what effective dates, tax laws, regulations and rulings may be enacted, promulgated or issued, which could result in an increase in our or our stockholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law.

Our ability to use our net operating loss carryforwards and certain other tax benefits may be limited and, as a result, our future tax liability may increase.

As of December 31, 2019, we had federal and California net operating loss carryforwards of \$168.2 million and \$168.2 million, respectively, some of which begin to expire in various amounts in 2027. As of December 31, 2019, we also had federal and California research and development tax credit carryforwards of \$13.4 million and \$8.5 million, respectively. The federal research and development tax credit carryforwards will begin to expire in 2035 unless previously utilized, while the California carryforwards will carry forward indefinitely. These net operating loss and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. In addition, in general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change net operating losses (NOLs) or tax credits, or NOLs or credits, to offset future taxable income or taxes. Generally, a change of more than 50 percentage points in the ownership of a corporation's stock, by value, over a three-year period constitutes an ownership change for U.S. federal income tax purposes. We have determined that we triggered an ownership change limitation in November 2009 and again in May 2015. We have determined that we do not believe there were any ownership changes from May 2015 through December 2019. We have not analyzed periods subsequent to December 2019. We may experience additional ownership changes as a result of shifts in our stock ownership in the future. Limits on our ability to use our pre-change NOLs or credits to offset U.S. federal taxable income could potentially result in increased future tax liability to us if we earn net taxable income in the future. The amount of NOLs generated in taxable periods beginning after December 31, 2020, that we are permitted to deduct in any taxable year is limited to 80% of our taxable income is determined without regard to the NOL deduction itself. U.S. federal a

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

- a) All information with respect to this item has been previously reported in our Current Report on Form 8-K.
- b) None.
- c) None.

### Item 3. Defaults Upon Senior Securities

None.

## Item 4. Mine Safety Disclosure

Not applicable.

### **Item 5. Other Information**

None.

## Item 6. Exhibits

Exhibit Number	Exhibit Title	Form	File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation of the Registrant, as currently in effect	S-1/A	333-190608	3.2	August 29, 2013
3.2	Certificate of Designation of Preferences, Rights and Limitations of Class A Convertible Preferred Stock	8-K	001-36076	3.1	November 29, 2016
3.3	Amended and Restated Bylaws of the Registrant, as currently in effect	S-1/A	333-190608	3.4	August 29, 2013
4.1	Specimen Common Stock Certificate	S-1/A	333-190608	4.1	August 29, 2013
10.1†	Collaboration and Option Agreement by and between the Registrant and Janssen Biotech, Inc., dated April 2, 2020	_	_	_	Filed herewith
10.2†	Stock Purchase Agreement by and between the Registrant and Johnson & Johnson Innovation – JJDC, Inc., dated April 2, 2020	_	_	_	Filed herewith
10.3†	Stock Purchase Agreement by and between the Registrant and Johnson & Johnson Innovation – JJDC, Inc., dated June 8, 2020	_	_	_	Filed herewith
31.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rules 13a-14 and 15-d-14 promulgated pursuant to the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	_	_	_	Filed herewith
32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	_	_	_	Filed herewith
101.INS	Inline XBRL Instance Document — the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.	_	_	_	Filed herewith
101.SCH	Inline XBRL Taxonomy Extension Schema Document	_	_	_	Filed herewith
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	_	_	_	Filed herewith
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	_	_	_	Filed herewith
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	_	_	_	Filed herewith
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	_	_	_	Filed herewith
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101).	_	_	_	Filed herewith

<sup>†</sup> Certain provisions of this Exhibit have been omitted as confidential information.

## **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.

## Fate Therapeutics, Inc.

Date: August 5, 2020

By: /s/ J. Scott Wolchko

J. Scott Wolchko

President and Chief Executive Officer and Director (Principal Executive Officer, Principal Financial Officer and Principal

Accounting Officer)

# **COLLABORATION AND OPTION AGREEMENT**

**BY AND BETWEEN** 

FATE THERAPEUTICS, INC.

**AND** 

JANSSEN BIOTECH, INC.

**DATED** 

**APRIL 2, 2020** 

[\*\*\*] Certain information in this exhibit has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the registrant if publicly disclosed.

		Page
ARTICLE 1	DEFINITIONS	1
ARTICLE 2	GOVERNANCE	26
2.1	JOINT RESEARCH COMMITTEE	26
2.2	JOINT MANUFACTURING COMMITTEE	27
2.3	JOINT STEERING COMMITTEE	28
2.4	MEETINGS AND MINUTES	28
2.5	SUBCOMMITTEES	29
2.6	LIMITATIONS OF COMMITTEE AUTHORITY	29
2.7	DISCONTINUATION OF COMMITTEES	29
2.8	ALLIANCE MANAGERS	29
ARTICLE 3	RESEARCH	30
3.1	OVERVIEW	30
3.2	JANSSEN ANTIGENS	30
3.3	RESEARCH PLANS	32
3.4	RESEARCH TERM EXTENSION	34
3.5	CONDUCT OF RESEARCH	34
3.6	RESEARCH COST	34
3.7	IND ENABLING STUDIES	35
3.8	RECORDS; REPORTS	36
3.9	SUBCONTRACTING	37
3.10	MATERIALS	37
3.11	POTENTIAL [***]	37
ARTICLE 4	COMMERCIAL OPTION	38
4.1	COMMERCIAL OPTION	38
4.2	DELIVERY OF IND DATA PACKAGES; PREPARATION OF MASTER IPSC BANK	38
4.3	OPTION EXERCISE	39
4.4	EFFECT OF OPTION EXERCISE	40
4.5	ONGOING ACTIVITIES	41
4.6	NON-EXERCISE OF OPTION	41
ARTICLE 5	GRANT OF RIGHTS; EXCLUSIVITY	42
5.1	LICENSES TO JANSSEN	42
5.2	LICENSE TO FATE	44

-i-

		Page
5.3	[***]	45
5.4	COLLABORATION INTELLECTUAL PROPERTY	46
5.5	SUBLICENSE	47
5.6	FUNCTIONAL IMPROVEMENTS; NEXT GENERATION CANDIDATES	48
5.7	PRODUCT TRADEMARKS; PATENT MARKING	50
5.8	THIRD PARTY IN-LICENSES	50
5.9	NO IMPLIED LICENSES; RETAINED RIGHTS; GOVERNMENT RIGHTS	50
5.10	EXCLUSIVITY AND OTHER RESTRICTIONS	51
ARTICLE 6	FATE OPT-IN OPTION	52
6.1	GRANT OF FATE OPT-IN OPTION	52
6.2	DELIVERY OF POC DATA PACKAGES	53
6.3	EXERCISE OF FATE OPT-IN OPTION	53
6.4	CONSEQUENCES OF EXERCISE OF FATE OPT-IN OPTION	54
ARTICLE 7	DEVELOPMENT AND COMMERCIALIZATION	54
7.1	GENERAL	54
7.2	RESTRICTION ON [***]	54
7.3	STANDARDS OF CONDUCT; RECORDS	54
7.4	DEVELOPMENT REPORTS	54
7.5	COMMERCIALIZATION REPORTS	54
7.6	DILIGENCE	55
7.7	SUBCONTRACTING	55
ARTICLE 8	REGULATORY	56
8.1	GENERAL	56
8.2	TRANSITION OF EXISTING REGULATORY FILINGS AND REGULATORY APPROVALS	56
8.3	RIGHT OF REFERENCE	58
8.4	REGULATORY ASSISTANCE	58
8.5	PHARMACOVIGILANCE AGREEMENT	59
ARTICLE 9	MANUFACTURE AND SUPPLY	59
9.1	CMC DEVELOPMENT	59
9.2	FATE MANUFACTURING FACILITIES; FACILITY MANUFACTURING SCHEDULES	61

		Page
9.3	MANUFACTURE AND SUPPLY OF EARLY STAGE CLINICAL SUPPLIES	61
9.4	MANUFACTURE AND SUPPLY OF PIVOTAL CLINICAL SUPPLIES AND INITIAL COMMERCIAL SUPPLIES	62
9.5	MANUFACTURE AND SUPPLY OF OTHER COMMERCIAL SUPPLIES	65
9.6	CELL BANKS	66
9.7	COMPLIANCE; SAFETY ISSUES	67
9.8	AUDITS	67
9.9	MANUFACTURING TECHNOLOGY TRANSFER	67
9.10	THIRD PARTY SUBCONTRACTORS	68
ARTICLE 10	FINANCIAL TERMS	69
10.1	UPFRONT PAYMENT	69
10.2	PAYMENTS DURING RESEARCH TERM	69
10.3	EFFECT OF COMMERCIAL OPTION EXERCISE	70
10.4	CLINICAL DEVELOPMENT AND REGULATORY MILESTONES	70
10.5	SALES MILESTONES	73
10.6	ROYALTY PAYMENTS	74
10.7	CMC DEVELOPMENT COSTS	77
10.8	PAYMENTS AFTER FATE EXERCISES THE FATE OPT-IN OPTION	77
10.9	MANNER OF PAYMENT	78
10.10	RECORDS	78
10.11	AUDITS	78
10.12	TAXES	79
ARTICLE 11	INTELLECTUAL PROPERTY	80
11.1	INVENTIONS	80
11.2	PATENT PROSECUTION	81
11.3	PATENT ENFORCEMENT	84
11.4	PATENT TERM EXTENSION	87
11.5	REGULATORY DATA PROTECTION	87
11.6	PATENT INVALIDITY CLAIMS	88
11.7	CLAIMED INFRINGEMENT	88
11.8	THIRD PARTY LICENSES	89
11.9	COMMON INTEREST DISCLOSURES	90

		Page
ARTICLE 12	CONFIDENTIALITY	91
12.1	NONDISCLOSURE	91
12.2	EXCEPTIONS	91
12.3	AUTHORIZED DISCLOSURE	91
12.4	TERMS OF THIS AGREEMENT	93
12.5	SECURITIES FILINGS	93
12.6	RELATIONSHIP TO CONFIDENTIALITY AGREEMENT	93
12.7	EQUITABLE RELIEF	93
12.8	RESEARCH PROGRAM INFORMATION AND SCIENTIFIC PUBLICATIONS	93
12.9	PUBLICITY	94
ARTICLE 13	REPRESENTATIONS, WARRANTIES, AND COVENANTS; DISCLAIMERS; LIMITATION OF LIABILITY	95
13.1	MUTUAL REPRESENTATIONS AND WARRANTIES	95
13.2	ADDITIONAL REPRESENTATIONS AND WARRANTIES OF FATE	95
13.3	ADDITIONAL REPRESENTATIONS AND WARRANTIES OF JANSSEN	96
13.4	MUTUAL COVENANTS	97
13.5	COMPLIANCE WITH ANTI-CORRUPTION LAWS	98
13.6	DISCLAIMERS	101
13.7	LIMITATION OF LIABILITY	101
ARTICLE 14	INDEMNITY AND INSURANCE	101
14.1	JANSSEN INDEMNITY	101
14.2	FATE INDEMNITY	102
14.3	INDEMNIFICATION PROCEDURE	102
14.4	INSURANCE	102
ARTICLE 15	TERM AND TERMINATION	103
15.1	TERM; EXPIRATION	103
15.2	TERMINATION FOR MATERIAL BREACH	104
15.3	JANSSEN UNILATERAL TERMINATION RIGHTS	104
15.4	TERMINATION FOR [***]	104
15.5	TERMINATION FOR INSOLVENCY	105
15.6	TERMINATION FOR [***]	106
15.7	CONSEQUENCES OF TERMINATION	107

		Page
15.8	SURVIVAL	108
ARTICLE 16	DISPUTE RESOLUTION	109
16.1	EXCLUSIVE DISPUTE RESOLUTION MECHANISM	109
16.2	RESOLUTION BY EXECUTIVE OFFICERS	109
16.3	ARBITRATION	109
16.4	PRELIMINARY INJUNCTIONS	111
16.5	PATENT DISPUTES	111
16.6	NO TRIAL BY JURY	111
ARTICLE 17	MISCELLANEOUS	111
17.1	SEVERABILITY	111
17.2	NOTICES	111
17.3	FORCE MAJEURE	112
17.4	ASSIGNMENT	112
17.5	FURTHER ASSURANCES	113
17.6	WAIVERS	113
17.7	GOVERNING LAW	113
17.8	RELATIONSHIP OF THE PARTIES	113
17.9	THIRD PARTY BENEFICIARY	114
17.10	ENTIRE AGREEMENT; AMENDMENT; EXHIBITS	114
17.11	INTERPRETATION; HEADINGS	114
17.12	COMPETITION LAW FILINGS	115
17.13	PERFORMANCE BY AFFILIATES	116
17.14	EFFECTS OF FATE CHANGE OF CONTROL	116
17.15	COUNTERPARTS; ELECTRONIC DELIVERY	117

#### **COLLABORATION AND OPTION AGREEMENT**

THIS COLLABORATION AND OPTION AGREEMENT (the "Agreement") is made and entered into as of April 2, 2020 (the "Effective Date"), by and between Fate Therapeutics, Inc., a Delaware corporation located at 3535 General Atomics Court, Suite 200, San Diego, California 92121, United States of America ("Fate"), and Janssen Biotech, Inc., a Pennsylvania corporation located at 800/850 Ridgeview Drive, Horsham, Pennsylvania 19044, United States of America ("Janssen"). Fate and Janssen are sometimes referred to herein individually as a "Party" and collectively as the "Parties".

#### RECITALS

**W**HEREAS, Fate has expertise in induced pluripotent stem cell (iPSC) biology and hematopoietic cell therapeutics, including NK cell and T-cell lymphocytes derived from iPSCs;

Whereas, Janssen has expertise in the research, development and commercialization of pharmaceutical products, including novel oncology target identification and antibody engineering;

**W**HEREAS, Janssen and Fate desire to collaborate using Fate's proprietary iPSC technology to research and preclinically develop allogeneic iPSC-derived NK cell and T-cell lymphocytes expressing a chimeric antigen receptor directed to specific antigens selected by the Parties as further described in this Agreement;

**W**HEREAS, Janssen desires to have an option to obtain an exclusive license to develop, manufacture and commercialize certain CAR-T cell and CAR-NK cell therapeutics developed by the Parties under this Agreement, subject to Fate having an option to participate in the commercialization of such cell therapeutics in the United States; and

**W**HEREAS, Fate desires to retain certain rights to manufacture the CAR-T cell and CAR-NK cell therapeutics for which Janssen may obtain the rights as described above;

#### **AGREEMENT**

Now, Therefore, in consideration of the foregoing and the mutual agreements set forth below, the Parties agree as follows:

# ARTICLE 1 DEFINITIONS

The terms in this Agreement (including the Profit Share Product Exhibit) with initial letters capitalized, whether used in the singular or the plural, shall have the meaning set forth below or, if not listed below, the meaning designated in places throughout this Agreement or the Profit Share Product Exhibit.

**1.1** "**Acquirer**" means any Third Party that is a counterparty in any Change of Control transaction and any of such Third Party's Affiliates.

- **1.2** "Affiliate" means, with respect to a Person, any other Person that directly or indirectly is controlled by, controls or is under common control with such first Person at the time the determination of affiliation is being made. For the purposes of this definition, the term "control" (including, with correlative meanings, the terms "controlled by" and "under common control with") as used with respect to any Person means (a) direct or indirect ownership of more than fifty percent (50%) of the voting securities, capital stock or equity interests of such Person or (b) possession, directly or indirectly, of the power to direct the management and policies of such Person, as applicable, whether through the ownership or control of voting securities, by contract or otherwise.
  - **1.3** "**Agreement**" has the meaning set forth in the Preamble.
- **1.4** "**Allogeneic**" means the use of cells or tissues derived, directly or indirectly, from any human subject other than the particular human subject to which such cells or tissues are administered or transplanted.
  - **1.5** "Annual Net Sales" means the Net Sales generated over any given Calendar Year.
- **1.6** "**Antigen Binding Domain**" means a protein fragment (such as an scFv) constructed from one (1) or more CDRs of an antibody, which protein fragment is Directed to a specific tumor-associated antigen.
- **1.7** "**Antigen Research Term**" means, with respect to each Janssen Antigen, the period beginning on the Effective Date (or, with respect to Janssen Antigen 3 and Janssen Antigen 4, the date that such Janssen Antigen is selected pursuant to Section 3.2.2) and ending the last day of the Initial Research Term (or, if the Agreement is terminated with respect to the applicable Janssen Antigen pursuant to Section 15.3 or Section 15.4, the effective date of termination of this Agreement with respect to such Janssen Antigen), as may be extended or reinstated pursuant to Section 3.4.1 or Section 3.4.2 for such Janssen Antigen.
- 1.8 "Biosimilar Product" means, with respect to a Licensed Product and on a country-by-country basis in the Territory, a product that (a) is marketed for sale in such country by a Third Party (not licensed, supplied or otherwise authorized by a Party or its Affiliates or Sublicensees); (b) contains, as an active pharmaceutical ingredient, a CAR-targeted T lymphocyte or CAR-targeted NK lymphocyte therapeutic that is the same as or a substantial equivalent of the active pharmaceutical ingredient contained in the corresponding Licensed Product; and (c) obtained marketing approval in such country by means of an abbreviated procedure that relies (i) in whole or in part on the safety and efficacy data contained in the BLA or MAA for such Licensed Product submitted by a Party in such country, and (ii) on establishing bioequivalence to the Licensed Product.
- **1.9** "**Business Day**" means a day other than Saturday, Sunday or any day on which commercial banks located in New York, New York are authorized or obligated by Laws to close.

- **1.10** "Calendar Quarter" means a quarter based on the Janssen Parent Universal Calendar for that quarter (a copy of which is attached hereto as **Exhibit 1.10**); *provided*, *however*, that (a) the first Calendar Quarter of any particular period shall extend from the commencement of such period to the end of the first complete Calendar Quarter thereafter; and (b) the last Calendar Quarter shall end upon the effective date of the expiration or termination of this Agreement.
- **1.11** "Calendar Year" means a year based on the Janssen Parent Universal Calendar for that year (a copy of which is attached hereto as <u>Exhibit 1.10</u>); *provided*, *however*, that (a) the first Calendar Year of the Term shall begin on the Effective Date and end on the last day of Calendar Year 2020 and (b) the last Calendar Year of the Term shall begin on the first day of the Calendar Year in which this Agreement expires or terminates and end on the effective date of expiration or termination of this Agreement.
  - **1.12 "CAR Cell Construct"** means a CAR-NK Cell or CAR-T Cell, as applicable.
  - **1.13 "CAR Cell Type"** refers to the cell type distinction between CAR-NK Cells and CAR-T Cells.
- **1.14** "CAR-NK Cells" means Allogeneic NK Cells expressing a CAR that are derived from iPSCs, which iPSCs may be in the form of a clone, a composition of cells, a cell line, a master cell bank or a working cell bank.
- **1.15** "CAR-T Cells" means Allogeneic T Cells expressing a CAR that are derived from iPSCs, which iPSCs may be in the form of a clone, a composition of cells, a cell line, a master cell bank or a working cell bank.
- **1.16** "**CD34 Composition**" means a CD34 positive hematopoietic cell or a population of CD34 positive hematopoietic cells, which: (a) may be in the form of a clone, a composition of cells, a cell line, a master cell bank or a working cell bank; and (b) are derived from iPSCs, which may be in the form of a clone, a composition of cells, a cell line, a master cell bank or a working cell bank.
- **1.17** "CD34 Composition Process" means any and all processes and protocols developed and used to differentiate iPSCs into CD34 Compositions and to characterize, compare, select, maintain, expand, test, qualify, cryopreserve, store, and thaw such CD34 Compositions, but for clarity does not include iPSC Generation, Cell Bank Process or the processes and protocols developed and used to differentiate CD34 Compositions into CAR-NK Cells and CAR-T Cells and the further expansion and formulation of such CAR-NK Cells and CAR-T Cells.
- **1.18** "CD34 Composition Process Development" means any and all activities undertaken to improve and further develop the CD34 Composition Process.
- **1.19** "CD34 Composition Manufacturing" means the Manufacture of a CD34 Composition using a Master iPSC Bank through the practice of the CD34 Composition Process.
  - **1.20 "CDR"** means the complementarity determining regions of an antibody.

- **1.21** "Cell Bank Process" means any and all processes and protocols developed and used to create a master cell bank or working cell bank of iPSCs and to characterize, compare, select, maintain, expand, test, qualify, cryopreserve, store, and thaw such master cell bank or working cell bank, but for clarity does not include iPSC Generation or CD34 Composition Process.
- **1.22** "Cell Bank Process Development" means any and all activities undertaken to improve and further develop the Cell Bank Process.
- **1.23 "Change of Control"** means, with respect to a Party, the direct or indirect occurrence of any of the following:
- completion of a merger, consolidation, stock sale, reorganization, amalgamation, arrangement, (a) share exchange, tender or exchange offer, private purchase, business combination, recapitalization, issuance of securities or other similar transaction or series of transactions involving such Party, a result of which either (i) the stockholders of such Party immediately preceding such transaction hold less, directly or indirectly, than 50% of the outstanding shares, or less than 50% of the outstanding voting power, of the ultimate company or entity resulting from such transaction immediately after the consummation thereof (including a company or entity which as a result of such transaction owns the then outstanding securities of such Party or all or substantially all of such Party's assets, either directly or through one or more subsidiaries), or (ii) any single Third Party Person or group (within the meaning of the U.S. Securities Exchange Act of 1934 and the rules of the SEC thereunder as in effect, referred to as a "Group") holds 50% or more, directly or indirectly, of the outstanding shares or voting power of the ultimate company or entity resulting from such transaction immediately after the consummation thereof (including a company or entity which as a result of such transaction owns the then outstanding securities of such Party or all or substantially of such Party's assets, either directly or through one or more subsidiaries); provided, however, solely with respect to clause (a)(i) and without limitation of the remainder of this Section 1.23, excluding a bona fide equity financing transaction or a series of bona fide equity financing transactions in which such Party issues shares of common stock in exchange for cash in one or more public underwritten offering(s);
- **(b)** the direct or indirect acquisition (including by means of a tender offer or an exchange offer) by any Third Party or Group of beneficial ownership, or the right to acquire beneficial ownership, or formation of any Third Party Group which beneficially owns or has the right to acquire beneficial ownership, of 50% or more of either the outstanding voting power or the then outstanding shares of such Party, in each case on a fully diluted basis;
- (c) individuals who, as of the date hereof, constitute the Board of Directors of a Party (the "Incumbent Board") cease for any reason to constitute at least a majority of the Board of Directors of such Party (*provided*, *however*, that any individual becoming a director subsequent to the date hereof whose election, or nomination for election by such Party's shareholders, was approved by a vote of at least a majority of the directors then comprising the Incumbent Board shall be considered as though such individual were a member of the Incumbent Board, but excluding, for this purpose, any such individual whose initial assumption of office occurs as a result of an actual or threatened election contest with respect to the election or removal of directors or other actual or threatened solicitation of proxies or consents by or on behalf of any person other than the Board of Directors of such Party);

- **(d)** the adoption of a plan relating to the liquidation or dissolution of a Party, other than in connection with a corporate reorganization (without limitation of clause (a) above); or
- **(e)** the sale or disposition to a Third Party of all or substantially all the assets of such Party (determined on a consolidated basis), including such Party's assets related to the Collaboration Candidates and Licensed Products.
- **1.24** "Chimeric Antigen Receptor" or "CAR" means a recombinant synthetic modular fusion protein receptor that comprises an Antigen Binding Domain, a spacer domain, a transmembrane domain, and an intracellular signaling domain (such as a domain containing immunoreceptor tyrosine-based activation motifs (ITAMs)).
- 1.25 "Clearance Date" means the date on which the following conditions are met with respect to a Competition Law Filing under Section 4.3.2: (a) the waiting period under the HSR Act or other applicable Competition Law shall have expired or earlier been terminated; (b) no injunction (whether temporary, preliminary or permanent) prohibiting effectiveness of exercise of the Commercial Option or the [\*\*\*], as applicable, shall be in effect; (c) no judicial or administrative proceeding opposing such effectiveness shall be pending; and (d) no requirements or conditions shall have been imposed by the DOJ, FTC or other applicable governmental authority in connection with such Competition Law Filing, other than requirements or conditions that are consented to in writing by the Party on whom such requirements or conditions are imposed.
- **1.26** "Clinical Trials" means Phase I Trials, Phase II Trials, Phase III Trials, Phase IV Trials, or variations of such trials (for example, phase II/III studies).
  - **1.27** "Close Homolog" means, with respect to an Antigen Binding Domain, [\*\*\*].
- **1.28** "CMC Development" means CD34 Composition Process Development and Product Process Development. For clarity, CMC Development does not include iPSC Generation or Cell Bank Process Development.
- 1.29 "CMC Development Costs" means CMC Development FTE Costs and Out-of-Pocket Expenses incurred by each Party and its Affiliates in conducting activities under a CMC Development Plan. CMC Development Costs shall exclude (i) Shared Development Costs, (ii) Allowable Expenses, (iii) any payments made pursuant to the Profit Share Product Exhibit, (iv) capital expenditures for facility or equipment; *provided*, *however*, that Out-of-Pocket Expenses shall include capital expenditures for equipment used exclusively for the performance of activities under a CMC Development Plan and, then, only to the extent such capital expenditures are depreciable, and (v) costs attributable to general corporate activities, executive management, investor relations, treasury services, business development, corporate government relations, external financial reporting and other general and administrative overhead.
- **1.30** "CMC Development FTE" means work carried out by one or more qualified employees, contractors or consultants of a Party or its Affiliates devoted to or in direct support of the CMC Development Plan activities, where the work of a CMC Development FTE shall be considered full-time based on [\*\*\*] hours of work and, in the case of work that is less than full-time, will be pro-rated based on the actual number of hours expended by such CMC Development FTE. CMC Development FTE does not include work performed by personnel performing administrative and corporate functions (including human resources, finance, legal and investor relations).

- **1.31 "CMC Development FTE Costs"** means the amount calculated by multiplying [\*\*\*] by [\*\*\*].
- **1.32** "CMC Development FTE Rate" means a rate of [\*\*\*] per full-time CMC Development FTE per Calendar Year; *provided*, *however*, that such rate shall be increased or decreased annually beginning on January 1, 2021 by the percentage increase or decrease in the CPI between the last day of the most recently completed Calendar Year and December 31, 2019, plus [\*\*\*] or an alternative methodology that is mutually agreed to by both Parties. The CMC Development FTE Rate is "fully burdened" and will cover employee salaries (excluding stock-based compensation), benefits, utilities, facilities, and travel expenses.
- **1.33 "Collaboration Candidate"** means, with respect to a Janssen Antigen, any CAR Cell Construct generated by Fate during the applicable Antigen Research Term, where the CAR expressed by such CAR Cell Construct incorporates [\*\*\*].
- **1.34** "Combination Product" means a product, pharmaceutical preparation or formulation that contains (a) a Licensed Product and (b) at least one (1) additional therapeutically active pharmaceutical ingredient other than a Licensed Product, where all of the foregoing ingredients are presented, labelled for use together, and sold together, in the same therapeutic preparation or formulation or as part of a co-packaged or label-directed combination therapy, as a single unit for a single price and invoiced as a single unit for a single price. For clarity, drug delivery vehicles, adjuvants and excipients are hereby deemed not to be "therapeutically active pharmaceutical ingredients," and their presence in itself shall not be deemed to create a Combination Product.
- **1.35** "Commercialization" or "Commercialize" means marketing, promoting, detailing, distributing, importing, exporting, offering for sale or selling a drug or biological product, including Medical Affairs Activities, regulatory activities directed to obtaining pricing and reimbursement approvals, reimbursement/access services, health policy/advocacy activities and price calculations and related reporting to Governmental Authorities, and interacting with Regulatory Authorities with respect to the foregoing. Commercialization does not include any activities that are Development activities or Manufacturing activities.
- **1.36** "**Commercialization Approval**" means, with respect to a Licensed Product and any country or regulatory jurisdiction, receipt of both: (i) approval of a Marketing Approval Application for such Licensed Product by the applicable Regulatory Authority in such country or regulatory jurisdiction; and [\*\*\*]
  - (a) [\*\*\*]
  - **(b)** [\*\*\*]
  - (c) [\*\*\*]
  - (d) [\*\*\*<sup>\*</sup>
  - (e) [\*\*\*]

- **1.37** "[\*\*\*] Efforts" means [\*\*\*].
- **1.38** "Committee" means (a) each of the JRC and JMC; (b) if Janssen exercises a Commercial Option, each of the JSC and JMC; and (c) if Fate exercises the Fate Opt-In Option, the JSC, JMC, JDC, and USJCC and JFC.
  - **1.39 "Competing Product"** means, with respect to a Janssen Antigen, [\*\*\*].
- **1.40** "Confidential Information" means all non-public or proprietary information (a) disclosed orally, visually, in writing or in other form by or on behalf of a Party (or an Affiliate or representative of such Party) to the other Party (or to an Affiliate or representative of such other Party) pursuant to or in connection with this Agreement, whether prior to, on or after the Effective Date, or (b) otherwise expressly deemed to be "Confidential Information" of a Party under another provision of this Agreement.
- 1.41 "Controlled" or "Control" means, when used in reference to Know-How, Patents, Confidential Information, or intellectual property rights, the legal authority or right (either by ownership or license (other than a license granted pursuant to this Agreement)) of a Party (or any of its Affiliates) to grant a license or sublicense of such Know-How, Patents, Confidential Information, or intellectual property rights to the other Party, or to otherwise disclose such Know-How, Patents, Confidential Information, or intellectual property rights to the other Party, without violating or breaching the terms of any agreement with any Third Party, or misappropriating such Know-How, Patents, Confidential Information, or intellectual property rights of any Third Party, such Third Party agreement existing (a) as of the Effective Date or (b) subsequent to the Effective Date if (in the case of this clause (b)) such Party first acquired rights to such Know-How, Patents, Confidential Information, or intellectual property rights pursuant to such agreement.
- **1.42 "Cooperative Group"** means any cooperative group that is funded by the U.S. National Cancer Institute Clinical Trials Cooperative Group Program or any similar cooperative group in any country outside the U.S.
- 1.43 "Cost of Goods" or "COGS" means a Party's reasonable internal and Third Party costs incurred in manufacturing or acquisition of Collaboration Candidate or Licensed Product, determined in accordance with such Party's standard cost accounting policies that are in accordance with GAAP and consistently applied across all of such Party's manufacturing network to other products that the Party manufactures. COGS does not include any CMC Development Costs. "COGS" are comprised of Standard Cost of Goods Manufactured, Cost Variances, and Other Costs Not Included in Standard, where:
  - (a) [\*\*\*]
  - **(b)** [\*\*\*]
  - (c) [\*\*\*]

- **1.44** "Cover" means, with respect to a Licensed Collaboration Candidate or a Licensed Product (including, in each case, its Precursor iPSC, Master iPSC Bank or CD34 Composition), that, in the absence of a license granted under or ownership of such Valid Claim, the making, use, offering for sale, sale, or importation of such Licensed Collaboration Candidate or Licensed Product (including, in each case, its Precursor iPSC, Master iPSC Bank or CD34 Composition) would or is reasonably likely to infringe such Valid Claim (or, for any pending patent claim, infringe such Valid Claim as if it were issued), in each case for the purpose of Royalty Term without regard to the research exemption under the Hatch-Waxman Act.
- **1.45** "Currency Hedge Rate" means the Janssen Parent currency hedge rate, which is the result of the effectively performed currency hedging at Janssen Parent for the upcoming Calendar Year and will be set up once a Calendar Year and will remain constant throughout such Calendar Year. The Janssen Parent currency hedge rate is calculated as a weighted average hedge rate of the outstanding external foreign currency forward hedge contracts of Janssen Parent with Third Party banks.
- 1.46 "Development" means: (a) all non-clinical, preclinical and clinical drug development activities and processes to support Commercialization Approval of a drug or biological product, including toxicology, pharmacology, and other non-clinical and preclinical efforts, test method development, statistical analysis, Clinical Trials (including post-marketing commitments), and Medical Affairs Studies; (b) CMC Development activities; (c) regulatory activities relating to Clinical Trials and CMC Development activities, including the preparation and submission of IND/CTAs; (d) regulatory activities in support of obtaining Commercialization Approval, including preparation and submission of information and Regulatory Filings to a Regulatory Authority, regulatory affairs, project management, drug safety surveillance and REMS programs as required by the FDA or other Regulatory Authorities; (e) Early Access Programs; and (f) pharmacovigilance activities with respect to a drug or biological product, including establishing, updating and maintaining of a global safety database. Development excludes all activities directed toward Manufacturing or Commercialization of Collaboration Candidates and Licensed Products. When used as a verb, "Develop" means to engage in Development.
- **1.47** "[\*\*\*] **Efforts**" means, with respect to each Party's obligations to conduct specific activities allocated to such Party under this Agreement, [\*\*\*].
  - **1.48** "Directed to" means, with respect to a particular antigen binding domain and an antigen, [\*\*\*].
- **1.49** "**Discontinued Collaboration Candidate**" means (a) each DC Collaboration Candidate that is deemed to be a Discontinued Collaboration Candidate pursuant to Section 3.7.3, provided that, when used in reference to a particular Janssen Antigen, Discontinued Collaboration Candidate shall only encompass such DC Collaboration Candidate incorporating a Janssen Antigen Binding Domain with respect to such Janssen Antigen; and (b) each Pre-IND Collaboration Candidate incorporating a Janssen Antigen Binding Domain that is deemed to be a Discontinued Collaboration Candidate pursuant to Section 3.7.5, 4.3.2 or 4.6.
  - **1.50 "Dollar"** or "\$" means the lawful currency of the United States.

- **1.51** "Early Access Program" or "EAP" means, with respect to any country, any program to provide patients with a drug or biological product before receipt of Marketing Approval and before First Commercial Sale in such country, in which program the use of the drug or biological product is not primarily intended to obtain information about the safety or effectiveness of such drug or biological product, including Treatment INDs / Protocols, Named Patient Programs and Compassionate Use programs. For clarity, an EAP with respect to a drug or biological product may continue to be performed following receipt of Marketing Approval of such drug or biological product and costs may continue to be incurred in accordance with the performance of such EAP after Marketing Approval.
  - **1.52 "Effective Date"** has the meaning set forth in the Preamble.
  - **1.53** "EMA" means the European Medicines Agency, or any successor agency thereto.
  - **1.54** "**Equivalent**" means: [\*\*\*].
- **1.55** "European Union" or "EU" means the countries of the European Economic Area, as it is constituted on the Effective Date and as it may be modified from time to time after the Effective Date; *provided, however*, that if the United Kingdom ceases to be a member of the European Union it shall continue to be treated as a country in the European Union for the purposes of this definition.
- 1.56 "Executive Officers" means: (a) with respect to Fate, its Chief Executive Officer (or a senior executive officer of Fate or its Affiliates designated by its Chief Executive Officer); and (b) with respect to Janssen, (i) if a matter pertains to the Development of a Collaboration Candidate, Licensed Collaboration Candidate or a Licensed Product, the Global Therapeutic Head, Oncology (or a senior executive officer of Janssen or its Affiliates designated by such officer), (ii) if a matter pertains to the Commercialization of a Licensed Product, the Global Commercial Strategy Leader, Oncology (or a senior executive officer of Janssen or its Affiliates designated by such officer), or (iii) if a matter pertains to the Manufacturing of a Licensed Collaboration Candidate or Licensed Product, President, Janssen Supply Group, LLC (or a senior executive officer of Janssen or its Affiliates designated by such officer). In the event that the position of any of the Executive Officers identified in this Section no longer exists due to a corporate reorganization, corporate restructuring or the like that results in the elimination of the identified position, the applicable Executive Officer shall be replaced with another executive officer with responsibilities and seniority comparable to the eliminated Executive Officer.
  - **1.57 "Existing Functional Elements"** means, individually and collectively: [\*\*\*].
  - **1.58 "Fate"** has the meaning set forth in the Preamble.
- **1.59 "Fate Platform Technology"** means Patents and Know-How Controlled by Fate or its Affiliates as of the Effective Date or at any time during the Term that comprise [\*\*\*].

- **1.60** "Fate Product Know-How" means all Know-How Controlled by Fate or its Affiliates as of the Effective Date or at any time during the Term that is reasonably necessary or useful for the Development, Manufacture or Commercialization of any Licensed Collaboration Candidate or Licensed Product (including, in each case, its Master iPSC Bank or CD34 Compositions), including any Fate Confidential Methods.
- 1.61 "Fate Product Patents" means all Patents Controlled by Fate or its Affiliates as of the Effective Date or, subject to Section 11.7.2(c), at any time during the Term that claim (a) the compositions of matter of any Licensed Collaboration Candidate or Licensed Product (including, in each case, its Master iPSC Bank and CD34 Compositions), or ingredients, manufacturing components, or intermediates thereof, (b) the use, or methods of manufacture, treatment or administration, of any Licensed Collaboration Candidate or Licensed Product (including, in each case, its Master iPSC Bank and CD34 Compositions) or (c) any Fate Product Know-How.
- **1.62** "Fate Research Know-How" means all Know-How Controlled by Fate or its Affiliates as of the Effective Date or during the Research Term that is reasonably necessary or useful for Janssen to perform its obligations as set forth under the Research Plans.
- **1.63** "Fate Research Patents" means all Patents Controlled by Fate or its Affiliates as of the Effective Date or, subject to Section 11.7.2(c), during the Research Term that are reasonably necessary or useful for a Party to perform its obligations as set forth under the Research Plans.
  - **1.64 "FDA"** means the U.S. Food and Drug Administration, or any successor agency thereto.
- **1.65 "Field"** means all uses, including all diagnostic, therapeutic, prognostic and prophylactic applications in humans.
- 1.66 "Filing of a Marketing Approval Application" means: (a) with respect to a BLA or a Supplemental Application to a BLA, the date on which FDA has completed its filing review of such BLA or Supplemental Application and has determined that it is sufficient to permit a substantive review (which shall be deemed to occur [\*\*\*] days after FDA's receipt of the application unless the FDA refuses to file the application, or the equivalent thereof in the event the FDA modifies such process after the Effective Date); and (b) with respect to an MAA filed with the EMA or a Supplemental Application to an MAA filed with the EMA, the date on which the CHMP validation period is complete.
- 1.67 "First Commercial Sale" means, with respect to a Licensed Product in a country, the first commercial sale of such Licensed Product to a Third Party in such country after Marketing Approval of such Licensed Product has been granted, or such marketing and sale is otherwise permitted, by the Regulatory Authority of such country. Sales for Clinical Trial purposes, Early Access Programs, registration samples or compassionate use shall not constitute a First Commercial Sale. In addition, sales of a Licensed Product by and between a Party and its Affiliates, licensees and Sublicensees, or between the Parties (or their respective Affiliates, licensees or Sublicensees) for eventual resale to a Third Party shall not constitute a First Commercial Sale.
  - **1.68** "Functional Improvement" means [\*\*\*].

- **1.69** "GAAP" means generally accepted accounting principles in the United States, consistently applied. Unless otherwise defined or stated, financial terms shall be calculated by the accrual method under GAAP.
- **1.70** "Good Clinical Practices" or "GCP" means the current standards for the conduct of Clinical Trials, as set forth in the applicable regulations and ICH guidance, including ICH E6, as amended from time to time, and such standards of good clinical practice as are required by the European Union and other organizations and governmental agencies in countries in which a Licensed Product is intended to be tested to the extent such standards are not less stringent than U.S. Good Clinical Practice.
- **1.71 "Good Laboratory Practices"** or **"GLP"** means the regulations set forth in 21 C.F.R. Part 58 and the requirements expressed or implied thereunder imposed by the FDA or (as applicable) any equivalent or similar standards in jurisdictions outside the United States, to the extent such standards are not less stringent than U.S. Good Laboratory Practice.
- **1.72** "Good Manufacturing Practices" or "GMP" means the part of quality assurance which ensures that products are consistently produced and controlled in accordance with the quality standards appropriate to their intended use as defined in 21 C.F.R. Parts 210 and 211, European Directive 2003/94/EC, Eudralex 4, Annex 16, and applicable U.S., European Union, Canadian, Japanese and ICH Guidance or regulatory requirements for a drug or biological product.
- **1.73** "Good Tissue Practices" or "GTP" means the part of quality assurance which ensures requirements governing the methods used in, and the facilities and controls used for, the manufacture of HCT/Ps, including all steps in recovery, donor screening, donor testing, processing, storage, labeling, packaging, and distribution as defined in U.S. subparts C and D of 21 CFR part 1271 or (as applicable) any equivalent or similar standards in jurisdictions outside the United States, to the extent such standards are not less stringent than U.S. Good Tissue Practice.
- **1.74** "**Governmental Authority**" means any national, federal, state or local government, or political subdivision thereof, or any multinational organization or authority or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, any court or tribunal (or any department, bureau or division thereof), or any governmental arbitrator or arbitral body.
- 1.75 "Improvement Period" means, with respect to a Licensed Product, the period beginning on the applicable Exercise Effective Date for the Licensed Collaboration Candidate contained in such Licensed Product and ending on the earlier of (a) the [\*\*\*] anniversary of the Exercise Effective Date for the Licensed Collaboration Candidate contained in such Licensed Product; or (b) the last day of the Exclusivity Period with respect to the applicable Janssen Antigen; provided, however, that if Janssen does not commence a Clinical Trial for any Licensed Product with respect to the applicable Janssen Antigen within [\*\*\*] years after the date on which the IND becomes effective in the U.S. under 21 C.F.R. 312.40 for the first such Licensed Product with respect to such Janssen Antigen, then the Improvement Period for each Licensed Product with respect to such Janssen Antigen shall end on the last day of such [\*\*\*] year period, unless Janssen does not commence a Clinical Trial during such [\*\*\*] year period due to Fate's failure to perform any of its obligations under this Agreement in a timely manner or due to a circumstance that is outside Janssen's reasonable control.

- **1.76** "IND/CTA" means (a) any Investigational New Drug Application, as defined in the United States Federal Food, Drug and Cosmetics Act, as amended from time to time, and the regulations promulgated thereunder, filed with the FDA pursuant to Part 312 of Title 21 of the U.S. Code of Federal Regulations, including any amendments thereto (an "IND"); and (b) any comparable filing(s) outside the United States (such as a CTA in the European Union) necessary to commence Clinical Trials, including any amendments thereto (a "CTA").
- **1.77 "IND Enabling Studies"** means all preclinical and non-clinical activities, conducted under GLP as necessary, the protocol and results of which are necessary to prepare a complete IND for a drug or biological product, including, to the extent necessary, PK/ADME studies, potency studies, pharmacodynamics, safety, toxicology, pharmacology, preformulation, and formulation development.
- **1.78 "Indication"** means the diagnosis, treatment or prevention of a discrete clinically recognized form of a disease. [\*\*\*]
- **1.79** "**Initial Research Term**" means the period commencing on the Effective Date and ending on the date that is the [\*\*\*] anniversary of the Effective Date.
- **1.80** "iPSC Generation" means any and all processes, protocols and activities developed and used to harvest somatic cells from donors and make, engineer, characterize, compare, select, maintain, expand, test, qualify, cryopreserve, store, and thaw iPSCs from such harvested cells, which iPSCs may be in the form of a clone, a collection of cells, a cell line, a master cell bank (including a Master iPSC Bank), or a working cell bank.
  - **1.81** "**Janssen**" has the meaning set forth in the Preamble.
- **1.82** "Janssen Antigen" means, individually and collectively, Janssen Antigen 1 and Janssen Antigen 2, and, if selected by Janssen, Janssen Antigen 3 and Janssen Antigen 4.
- **1.83** "Janssen Antigen Binding Domain" means, with respect to a Janssen Antigen: (a) up to [\*\*\*] Antigen Binding Domains, each of which: [\*\*\*].
  - **1.84** "Janssen Parent" means Johnson & Johnson.
- **1.85** "Janssen Product Know-How" means all Know-How Controlled by Janssen or its Affiliates as of the Effective Date or at any time during the Term that is actually used by Janssen (or that Janssen authorizes Fate to use during the course of conducting a Research Plan or the CMC Development Plan) for the CMC Development and/or Manufacture of any Licensed Collaboration Candidate or Licensed Product (including, in each case, its Master iPSC Bank or CD34 Compositions).
- **1.86** "Janssen Product Patents" means all Patents Controlled by Janssen or its Affiliates as of the Effective Date or at any time during the Term that claim (a) the compositions of matter of any Licensed Collaboration Candidate or Licensed Product (including, in each case, its Master iPSC Bank or CD34 Cell Intermediate), or ingredients, manufacturing components, or intermediates thereof, (b) methods of manufacture of any Licensed Collaboration Candidate or Licensed Product (including, in each case, its Master iPSC Bank or CD34 Compositions), or (c) any Janssen Product Know-How.

- **1.87** "Janssen Research Know-How" means all Know-How Controlled by Janssen or its Affiliates as of the Effective Date or during the Research Term that is reasonably necessary or useful for Fate to perform its obligations as set forth under the Research Plans, including any such Know-How relating to a Janssen Antigen Binding Domain.
- **1.88** "Janssen Research Patents" means all Patents Controlled by Janssen or its Affiliates as of the Effective Date or during the Research Term that are reasonably necessary or useful for a Party to perform its obligations as set forth under the Research Plans, including those that claim the compositions of matter of, or the method of making or using, any Janssen Antigen Binding Domain.
- **1.89** "**Know-How**" means technical, scientific and other information and know-how, including: (a) biological, chemical, pharmacological, toxicological, clinical, nonclinical, preclinical, manufacturing and clinical data; (b) assays; (c) trade secrets; (d) methods; (e) techniques; (f) processes; (g) procedures; (h) specifications; and (i) sourcing information, in each case that is not generally known to the public, but expressly excluding concepts and ideas.
- **1.90** "Laws" means all laws, statutes, rules, regulations, ordinances and other pronouncements, including any order by any court, regulatory agency or other Governmental Authority, having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision, domestic or foreign, in each case that are applicable to the activity in question and the jurisdiction in which it is conducted.
- **1.91** "Licensed Collaboration Candidate" means a Collaboration Candidate for which Janssen has exercised the Commercial Option in accordance with Section 4.3. For clarity, such Licensed Collaboration Candidate will remain a Collaboration Candidate (and all terms of this Agreement applicable to Collaboration Candidates will continue to apply to such Licensed Collaboration Candidate).
- **1.92** "Licensed Product" means a product, pharmaceutical preparation or formulation containing, as its active ingredient, a Licensed Collaboration Candidate. For clarity, if one or more product, pharmaceutical preparation or formulation contains, as its active ingredient, the same Licensed Collaboration Candidate for which Janssen has exercised the Commercial Option in accordance with Section 4.3, all such products, pharmaceutical preparations or formulations shall be considered the same Licensed Product so long as such products, pharmaceutical preparations or formulations do not also contain, as an active ingredient, a different Licensed Collaboration Candidate (in which case, such products, pharmaceutical preparations or formulations shall not be considered the same Licensed Product).
  - **1.93 "Major European Countries"** means France, Germany, Italy, Spain and the United Kingdom.
- **1.94** "**Major Markets**" means each of the following: United States, United Kingdom, Italy, Germany, France, Spain, People's Republic of China and Japan.

- **1.95** "Manufacturing" or "Manufacture" means activities directed to producing, manufacturing, processing, filling, finishing, packaging, labeling, quality assurance testing and release, shipping and storage of a product. For clarity, when used with respect to a Licensed Collaboration Candidate or a Licensed Product, Manufacturing shall include CD34 Composition Manufacturing and Product Manufacturing.
- **1.96 "Marketing Approval"** means approval of a Marketing Approval Application by the applicable Regulatory Authority.
- 1.97 "Marketing Approval Application" means: (a) a Biologics License Application submitted to the FDA pursuant to Section 351(a) of the Public Health Service Act and the regulations promulgated thereunder (a "BLA"); (b) an application for authorization to market or sell a biological product submitted to a Regulatory Authority in any country or jurisdiction in the OUS Territory, including, with respect to the European Union, 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 European Economic Area with respect to the decentralized procedure, mutual recognition or any national approval procedure (an "MAA"); or (c) with respect to any biological product for which a BLA or MAA (as defined in the preceding clauses (a) and (b)) has previously been approved by the applicable Regulatory Authority, an application to supplement or amend such BLA or MAA to expand the approved label for such biological product to include use of such biological product for an additional indication (a "Supplemental Application").
- **1.98** "Master iPSC Bank" means, with respect to a particular Licensed Collaboration Candidate and Licensed Product containing such Licensed Collaboration Candidate, a master induced pluripotent stem cell bank corresponding to such Licensed Collaboration Candidate, including any working cell bank corresponding thereto and the iPSC clones contained therein, that is established under this Agreement and is used as the starting material for the Manufacture of such Licensed Collaboration Candidate and Licensed Product containing such Licensed Collaboration Candidate.
- 1.99 "Medical Affairs Activities" means activities directed to interacting with physicians and other healthcare professionals who utilize or conduct research related to a drug or biological product, including: medical and scientific information; responding to external inquiries or complaints; pharmacovigilance activities; medical education; Health Economics and Outcomes Research (HECOR, HEMAR); speaker programs; advisory boards; grants, fellowships and sponsorships; drug safety; local country government affairs; deployment of field-based medical science liaisons (MSLs); MD's in the field (separate from medical science liaisons); publications; medical communications; field medical education; registries; advocacy support; and slide libraries/kits, reprints and publication planning, but excluding activities directed toward the conduct or support of Medical Affairs Studies.
  - **1.100** "**Medical Affairs Study**" means any of the following:
- (a) any Clinical Trial that is sponsored and conducted by a Cooperative Group as sponsor-investigator (a "Cooperative Group Study") that is supported or enabled by a Party or one of its Affiliates or Sublicensees;

- **(b)** any Clinical Trial that is sponsored and conducted by a Third Party as a sponsor-investigator, other than a Cooperative Group Study (sometimes referred to as an "**Investigator Initiated Study**" or "**IIS**") that is supported or enabled by a Party or one of its Affiliates or Sublicensees; or
- (c) any Clinical Trial that: (i) is sponsored and conducted by a Party or one of its Affiliates or Sublicensees as a sponsor; (ii) is not intended for use as a basis for obtaining Marketing Approval (e.g., for a further indication, label expansion or otherwise); and (iii) is not being conducted as a commitment made to or a requirement imposed by a Regulatory Authority as a condition of, or in connection with obtaining or maintaining, a Marketing Approval, including any Real World Evidence (RWE) study that is intended to support commercial efforts to secure and retain reimbursement, including Phase IV Trials.
- **1.101** "Natural Killer Cells" or "NK Cells" means innate lymphoid cells having the inherent ability to recognize and destroy stressed cells, including virus-infected and tumor cells, without prior sensitization to such transformed cells.
- **1.102** "Net Sales" means, with respect to a Licensed Product, the gross amounts invoiced on sales of such Licensed Product by a Party (it being understood that, for purposes of this definition, any such gross amounts invoiced by a Party's Affiliate, licensee or Sublicensee shall be deemed to be invoiced by such Party) to a Third Party purchaser in an armslength transaction, less the following customary deductions, determined in accordance with GAAP and standard internal policies, procedures, and accounting standards consistently applied throughout the Party recording such sales to calculate revenue for financial reporting purposes, including deductions actually taken, paid, accrued, allocated or allowed based on good faith estimates, with respect to such sales (and consistently applied as set forth below):
- (a) normal and customary trade, cash or quantity discounts, allowances, wholesaler and pharmacy fees and credits allowed or paid, in the form of deductions actually allowed or actually paid with respect to sales of such Licensed Product (to the extent not already reflected in the amount invoiced) excluding commissions for commercialization;
- **(b)** excise taxes, use taxes, tariffs, sales taxes and customs duties, or other government charges imposed on the sale of such Licensed Product (but specifically excluding, for clarity, any income taxes assessed against the income arising from such sale) (including VAT, but only to the extent that such VAT taxes are not reimbursable or refundable);
- **(c)** outbound freight, shipment and insurance costs to the extent included in the price and separately itemized on the invoice:
- (d) compulsory and negotiated payments and cash rebates imposed on sales of such Licensed Product paid to a Governmental Authority (or agent thereof) pursuant to governmental regulations by reason of any national or local health insurance program or similar program, including pay-for-performance agreements, risk sharing agreements as well as government levied fees as a result of the PPACA;

- **(e)** retroactive price reductions, credits or allowances actually granted upon rejections or returns of such Licensed Product, including for recalls or damaged good and billing errors;
- (f) rebates, charge backs and discounts (or equivalent thereof) actually granted to managed health care organizations, pharmacy benefit managers (or equivalent thereof), federal, state/provincial, local or other governments, or their agencies or purchasers, reimbursers, or trade customers;
- **(g)** actual bad debt write-off attributable directly to the sale of such Licensed Product (*provided* that any such amounts subsequently recovered will be included in Net Sales for the Calendar Quarter in which recovered); and
- **(h)** coupons, discount/rebates associated with co-pay cards or the appropriate share of other patient support contributions or investments accounted for in gross to net.

All aforementioned deductions shall only be allowable to the extent they are commercially reasonable, and shall be determined, on a country-by-country basis, as incurred in the ordinary course of business in type and amount consistent with the Party's, the Affiliate's, licensee's or Sublicensee's (as the case may be) business practices consistently applied across its product lines and accounting standards and verifiable. All such discounts, allowances, credits, rebates and other deductions shall be fairly and equitably allocated to such Licensed Product and other products of the Party and its Affiliates, licensees and Sublicensees such that such Licensed Product does not bear a disproportionate portion of such deductions.

Sales of a Licensed Product by and between a Party and its Affiliates, licensees and Sublicensees, or between the Parties (or their respective Affiliates, licensees or Sublicensees) for eventual resale to Third Parties are not sales to Third Parties and shall be excluded from Net Sales calculations.

In the event a Licensed Product is a Combination Product, [\*\*\*]. Payments related to such Combination Product under this Agreement, including royalty payments, will be calculated, due and payable based only on such allocated Net Sales.

- **1.103** "OUS Territory" means the entire world and all countries, territories and possessions therein, excluding the U.S.
- **1.104** "Out-of-Pocket Expenses" means amounts paid by or on account of a Party to Third Party vendors or contractors for supplies and materials for use, or for services provided by them, directly in the performance of activities relating to the Collaboration Candidates and Licensed Products under this Agreement (or other activities for which sharing of Out-of-Pocket Expenses is otherwise specified in this Agreement). For clarity, Out-of-Pocket Expenses do not include: (a) payments for the Parties' or their Affiliates' salaries or benefits, benefits, utilities, travel expenses, general office supplies, insurance, information technology, capital expenditures (unless such capital expenditures are used exclusively for the performance of activities under a Research Plan and, then, only to the extent such capital expenditures are depreciable by Fate), or the like; or (b) amounts paid relating to activities that were not performed under this Agreement.

- **1.105** "Patents" means patents and patent applications and (a) any foreign counterparts thereof, (b) all divisionals, continuations, continuations in-part thereof or any other patent application claiming priority directly or indirectly to (i) any such specified patents or patent applications or (ii) any patent or patent application from which such specified patents or patent applications claim direct or indirect priority, and (c) all patents issuing on any of the foregoing, and any foreign counterparts thereof, together with all registrations, reissues, re-examinations, renewals, supplemental protection certificates, or extensions of any of the foregoing, and any foreign counterparts thereof.
- **1.106 "Person"** means any individual, firm, corporation, partnership, limited liability company, trust, business trust, joint venture, governmental authority, association or other entity.
  - **1.107 "Phase 1 Proof-of-Concept Date"** means, with respect to a particular Licensed Product, [\*\*\*].
- **1.108 "Phase I Trial"** means a human clinical trial in any country, the principal purpose of which is a preliminary determination of safety in healthy individuals or patients, as more fully defined in 21 C.F.R. § 312.21(a), or its successor regulation, or the equivalent in any foreign country.
- **1.109 "Phase II Trial"** means a human clinical trial in any country that is intended to explore a variety of doses, dose response, and duration of effect, and to generate initial evidence of clinical safety and activity in one or more target patient populations, as more fully described in 21 C.F.R. § 312.21(b), or its successor regulation, or the equivalent in any foreign country.
- **1.110 "Phase III Trial"** means a human clinical trial in any country in one or more target patient populations that is (a) conducted at a dose and schedule for which evidence suggesting clinical safety and effectiveness of the Licensed Product has been obtained in such patient population(s) pursuant to one or more previous human clinical trials, and (b) conducted to gather additional information about effectiveness and safety of such dose and schedule in such patient population(s) as needed to evaluate the benefit-risk relationship of the drug and to provide an adequate basis for submission of a Marketing Approval Application to the FDA or other Regulatory Authority, as more fully defined in 21 C.F.R. § 312.21(c), or its successor regulation, or the equivalent in a country other than the United States.
- **1.111 "Phase IV Trial"** means a human clinical trial commenced after receipt of Marketing Approval in the country for which such trial is being conducted and that is conducted within the parameters of the Marketing Approval for the Licensed Product. Phase IV Trials may include epidemiological studies, modeling and pharmacoeconomic studies of a Licensed Product and post-marketing surveillance studies.
  - **1.112 "PPACA"** means the U.S. Patient Protection and Affordable Care Act.
- **1.113 "Precursor iPSC"** means, with respect to a Collaboration Candidate (including a Licensed Collaboration Candidate), an engineered iPSC clone, which may exist in various stages of expansion (e.g., a clone, in a collection of cells, in a cell line or in a master cell bank) and may be used for the generation of a CD34 Composition and then subsequently into such Collaboration Candidate.

- **1.114 "Prior CDA"** means the Confidential Disclosure Agreement between Fate and Janssen's Affiliate, having an effective date of November 21, 2018, as amended on November 14, 2019.
- **1.115 "Product Domain Names and Websites"** means any and all domain names and websites registered for use in association solely with the Licensed Products and the Product Trademarks, excluding website content.
- **1.116 "Product Manufacturing"** means the Manufacture of CAR-T Cells and CAR-NK Cells (as applicable), which are made from a CD34 Composition Manufactured using a Master iPSC Bank, through the practice of the Product Process. For clarity, Product Manufacturing does not include iPSC Generation, Cell Bank Process, or CD34 Composition Manufacturing.
- **1.117 "Product Process"** means any and all processes and protocols developed and used to differentiate CD34 Compositions into CAR-NK Cells and CAR-T Cells and the products containing such CAR Cell Types, including the development of differentiation processes and protocols, test methods, stability testing, process validation, process scale-up, formulation development, delivery system development, quality assurance and quality control development, and other related activities. For clarity, Product Process does not include iPSC Generation, Cell Bank Process or CD34 Composition Process.
- **1.118 "Product Process Development**" means any and all activities undertaken to improve and further develop the Product Process. For clarity, Product Process Development does not include iPSC Generation, Cell Bank Process Development or CD34 Composition Process Development.
- **1.119 "Product Trademarks"** means any trademark, trade name or service mark (whether registered or unregistered) used on, with, or to refer to a Licensed Product or used with patient support or other information or services or promotional materials in association with a Licensed Product, and all intellectual property rights residing in the foregoing.
- **1.120 "Profit Share Product"** means a Licensed Product for which Fate has exercised the Fate Opt-In Option in accordance with Section 6.3 and for which Fate has not [\*\*\*]. For clarity, if one or more product, pharmaceutical preparation or formulation contains, as its active ingredient, the same Licensed Collaboration Candidate, all such products, pharmaceutical preparations or formulations shall be considered the same Profit Share Product so long as such products, pharmaceutical preparations or formulations do not also contain, as an active ingredient, a different Licensed Collaboration Candidate (in which case, such products, pharmaceutical preparations or formulations shall not be considered the same Profit Share Product).
- **1.121** "**Profit Share Term**" means, with respect to a Profit Share Product, the period of time commencing on the Opt-In Exercise Date with respect to such Profit Share Product and ending on the earlier of (a) [\*\*\*] and (b) the last day of the Term with respect to such Profit Share Product.
  - **1.122** "Registration Study" means any Clinical Trial of a Licensed Product for which [\*\*\*].

- **1.123** "**Regulatory Approvals**" means, with respect to any Licensed Product in any jurisdiction, any and all approvals (including Marketing Approvals and Commercialization Approvals), licenses (including an import license), registrations and authorization from any Regulatory Authority that are required under applicable Law or reasonably necessary to Develop, Manufacture or Commercialize a drug or biological product in any country or jurisdiction for one or more uses, and all amendments and supplements thereto.
- **1.124** "**Regulatory Authority**" means any national or supranational governmental authority, including the FDA or EMA, or any successor agency thereto, that has responsibility in countries in the Territory over the Development, Manufacture or Commercialization of a Collaboration Candidate or a Licensed Product.
- 1.125 "Regulatory Exclusivity" means any exclusive marketing rights or data protection or other exclusivity rights conferred by any Regulatory Authority with respect to a drug or biological product that prevent (i) such Regulatory Authority from granting any regulatory approval of a Third Party product that has a composition that is the same as or substantially identical to the composition of such biological product; or (ii) a Third Party from making a cross reference to data held by such Regulatory Authority including orphan drug exclusivity, pediatric exclusivity, rights conferred in the U.S. under Section 351 of the Public Health Service Act, 42 U.S.C. §262, the Drug Price Competition and Patent Term Restoration Act (21 U.S.C. §355), as amended, the PPACA or in the European Union under Directive 2001/83/EC, as amended, and Regulation (EC) No. 1901/2006, as amended, or rights similar thereto in other countries or regulatory jurisdictions. If a Regulatory Authority confers more than one type of exclusivity with respect to a biological product in a country or jurisdiction (e.g., the FDA grants both biologic drug reference product exclusivity and orphan drug exclusivity with respect to such biological product), "Regulatory Exclusivity" will be deemed to apply to such biological product in such country or jurisdiction so long as any exclusivity granted to such biological product prevents such Regulatory Authority from granting any regulatory approval of a Third Party product that is a Biosimilar Product or making any cross reference to data held by such Regulatory Authority.
- **1.126** "**Regulatory Filings**" means any documentation comprising or relating to or supporting any Regulatory Approval with respect to a drug or biological product, or its use or potential use in humans, including any documents or reports submitted to any Regulatory Authority and all supporting data, including IND/CTAs, Marketing Approval Applications and all correspondence with any Regulatory Authority with respect to any drug or biological product (including minutes of any meetings, telephone conferences or discussions with any Regulatory Authority).
- **1.127** "**Related Licensed Products**" means, with respect to a Profit Share Product, any other Licensed Products with respect to the same Janssen Antigen as such Profit Share Product. For example, if the Profit Share Product is a Licensed Product with respect to Janssen Antigen 2, any other Licensed Products with respect to Janssen Antigen 2 are Related Licensed Products. For clarity, a Related Licensed Product may be of the same CAR Cell Type or different CAR Cell Type from the Profit Share Product.

- **1.128** "**Research**" means all scientific investigation, preclinical and non-clinical activities relating to identifying, generating, testing and optimizing a Collaboration Candidate. When used as a verb, "**Research**" means to engage in Research.
- **1.129** "Research Costs" means Research FTE Costs and Out-of-Pocket Expenses incurred by a Party and its Affiliates in conducting activities under the Research Plans. Research Costs shall exclude [\*\*\*], and (v) costs attributable to general corporate activities, executive management, investor relations, treasury services, business development, corporate government relations, external financial reporting and other general and administrative overhead.
- **1.130** "Research FTE" means work carried out by one or more qualified employees, contractors or consultants of a Party or its Affiliates devoted to or in direct support of the Research Plan activities, where the work of a Research FTE shall be considered full-time based on [\*\*\*] hours of work and, in the case of work that is less than full-time, will be pro-rated based on the actual number of hours expended by such Research FTE. Research FTE does not include work performed by personnel performing administrative and corporate functions (including human resources, finance, legal and investor relations).
  - **1.131 "Research FTE Costs"** means the amount calculated by [\*\*\*] by [\*\*\*].
- **1.132** "Research FTE Rate" means a rate of [\*\*\*] per full-time Research FTE per Calendar Year; *provided*, *however*, that such rate shall be increased or decreased annually beginning on [\*\*\*] by the percentage increase or decrease in the CPI between the last day of the most recently completed Calendar Year and [\*\*\*], plus [\*\*\*] or an alternative methodology that is mutually agreed to by both Parties. The Research FTE Rate is "fully burdened" and will cover employee salaries (excluding stock-based compensation), benefits, utilities, facilities, and travel expenses.
- **1.133** "**Research Program**" means, with respect to a Janssen Antigen, a program to be conducted by the Parties for the research and development of Collaboration Candidate(s) (including any Next Generation Candidate(s)) pursuant to the Research Plan for such Janssen Antigen.
- **1.134** "**Segregate**" means, with respect to any given product or program, to use [\*\*\*] Efforts to segregate activities directed to the exploitation of such product or program from activities directed to the exploitation of Collaboration Candidates or Licensed Products under this Agreement, including using [\*\*\*] Efforts to ensure that: [\*\*\*].
- **1.135 "Sublicense"** means a license or sublicense granted by written agreement pursuant to which a Third Party became a Sublicensee.
- **1.136** "Sublicensee" means (a) any Third Party granted a license or sublicense by Janssen to use, Developed, have Developed, make, have made and otherwise Manufacture, sell, offer to sell, have sold, promote, distribute, import, export and otherwise Commercialize a Licensed Product within a particular country or countries of the Territory, or (b) a Third Party granted a further Sublicense by a Sublicensee, in each case ((a) and (b)), in accordance with Section 5.5 and Section 9.10.

- **1.137** "**T Cells**" means any cytotoxic T lymphocytes that, through receptors found on their cell surface, inherently have the ability to recognize specific peptide antigens presented by major histocompatibility complex molecules and induce programmed cell death of target cells. For clarity, T Cells exclude regulatory or immunosuppressive T cells that generally suppress or downregulate induction and proliferation of effector T cells and maintain tolerance to self-antigens.
- **1.138** "**Tax**" or "**Taxes**" means any present or future taxes, levies, imposts, duties, charges, assessments or fees of any nature (including any interest thereon).
  - **1.139** "**Territory**" means the world.
  - **1.140 "Third Party"** means any Person other than Janssen, Fate, and their respective Affiliates.
  - **1.141** "**United States**" or "**U.S.**" means the United States of America and all its territories and possessions.
- 1.142 "Valid Claim" means, with respect to any country (a) a claim of an issued and unexpired patent (as may be extended through supplementary protection certificate or patent term extension or the like) to the extent such claim has not been revoked, held invalid or unenforceable by a patent office, court, or other governmental agency of competent jurisdiction in a final and non-appealable judgment (or judgment from which no appeal was taken within the allowable time period) and which claim has not been disclaimed, denied, or admitted to be invalid or unenforceable through reissue, re-examination, or disclaimer or otherwise (in each case other than as a result of any [\*\*\*] by Janssen for the original unexpired term as if such [\*\*\*] had not occurred), and (b) a pending claim of a pending patent application that (i) has not been abandoned or finally rejected without the possibility of appeal or refiling (other than as a result of any [\*\*\*] by Janssen for the original unexpired term as if such [\*\*\*] had not occurred), and (ii) has not been pending longer than [\*\*\*] years from the date of issuance of the first substantive patent office action considering patentability of such claim by the relevant patent office in the country or territory in which such claim is pending, after which time such pending claim shall cease to be a Valid Claim unless and until such claim becomes the claim of an issued patent pursuant to clause (a) above.

**1.143 Additional Definitions**. Each of the following definitions is set forth in the Section of this Agreement indicated below:

Defined Term	Section
AAA Rules	16.3.1
Acquiring Party	5.10.4
Additional Milestone Payment	10.4.3
Agreement	the Introduction
Alliance Manager	2.8
Allowable Expenses	Exhibit 6.4
Anti-Corruption Laws	13.5.1(a)
Antigen Selection Period	3.2.2

Defined Term	Section
Approved CMO	9.10.1
Background IP	5.4.2(b)
Back-Up Fate Facility	9.2.1
Bankruptcy Code	15.5.2
Biosimilar Application	11.3.4
BLA	1.97
Breaching Party	15.2
Claim Basis	14.3
Clinical Development Milestone Event	10.4.1
CMC Development Budget	9.1.2(c)
CMC Development Cost Report	10.7.2
CMC Development Plan	9.1.2(a)
CMO	9.10.1
COC IP	17.14.1
Co-Chair	2.4
co-exclusive (with Fate)	5.2.5
co-exclusive (with Janssen)	5.2.5
Commercial License	5.1.2(b)
Commercial Option	4.1
Commercial Option Start Date	4.3.1(b)
Commercial Option Term	4.3.1(b)
Commercial Supply Criteria	9.4.1(c)
Committee Matters	2.6
Competition Law Filings	4.3.2
Competition Laws	4.3.2
Compliant Clinical Manufacturing Facility	9.3.2
Compliant Commercial Manufacturing Facility	9.4.1(d)
Cooperative Group Study	1.100
Corresponding Antibody	1.83
CTA	1.76
Cure Period	15.2
DC Collaboration Candidates	3.7.1
DC Data Package	3.7.1
Disclosing Party	12.1
Disputes	16.1
DOJ	17.12(ii)
Early Stage Clinical Supplies	9.3.1
Early Stage Clinical Supply Agreement	9.3.3
Effective Date	the Introduction
Effective Royalty Rate	10.6.3(d)
embodiments	15.5.2
Exclusivity Period	5.10.1(b)
Exercise Effective Date	4.3.1(a)
Exercise Notice	4.3.1(a)

Defined Term	Section
Existing Agreements	11.8.1
Existing Fate Facility	9.2.1
Fate	the Introduction
Fate ABD Patent	11.2.1(d)
Fate Confidential Methods	Error! Reference source not found.
Fate Existing Technology	11.8.2(a)
[***]	[***]
[***]	[***]
Fate Indemnitees	14.1
Fate Licensor Patent	10.6.2
Fate Opt-In Option	6.1
Fate Patents	11.2.1(b)
Fate Product-Specific Patents	11.2.1(c)
[***]	[***]
Force Majeure	17.3
FTC	17.12(ii)
[***]	[***]
Group	1.23(a)
HSR Act	4.3.2
Improved Platform License	11.8.2(b)(i)
Incumbent Board	1.23(c)
IND	1.76
IND Data Package	4.2.1
IND Data Package Delivery Date	4.2.2
IND Selection Criteria	3.3.1(a)
Indemnification Claim	14.3
Indemnitee	14.3
Indemnitor	14.3
Infringement Action	11.3.2(a)
Infringement Claim	11.7
Initial Commercial Supplies	9.4.1(a)
Insolvency Event	15.5.1
Invalidity Claim	11.6
Inventions	11.1.1
Investigator Initiated Study or IIS	1.100
Janssen	the Introduction
Janssen Antigen 1	3.2.1
Janssen Antigen 2	3.2.1
Janssen Antigen 3	3.2.2
Janssen Antigen 4	3.2.2
Janssen Antigen Binding Domains with respect to a Janssen Antigen	3.1.3
[***]	[***]

Defined Term	Section
[***]	[***]
Janssen Indemnitees	14.2
Janssen Manufacturing Standards	9.1.1(a)
Janssen Profit Share Patents	11,2.2
JMC	2.2.1
Joint Inventions	11.1.2(c)
Joint Patent Costs	11.2.3(b)
Joint Patents	11.1.2(c)
Joint Product-Specific Patents	11.2.3(c)
[***]	[***]
JRC	2.1.1
JSC	2.3.1
Licensed Product DMFs	8.3.1
Losses	14.1
MAA	1.97
Manufacturing License	5.1.2(a)(ii)
Materials	3.10
Next Generation Candidate	5.6.2
Non-breaching Party	15.2
Opt-In Exercise Date	6.3
Option Exercise Payment	10.2.4
[***]	[***]
[***]	[***]
Other Income	Exhibit 6.4
Other Janssen ABD Product	11.2.1(d)
Party	the Introduction
patent counsel	11.2.1(b)
[***]	[***]
[***]	[***]
Pharmacovigilance Agreement	8.5.1
Pivotal Clinical and Commercial Supply Agreement	9.4.2(c)
Pivotal Clinical Supplies	9.4.1(a)
Planned Fate Facility	9.2.1
POC Data Package	6.2
POC Data Package Delivery Date	6.2(d)
Pre-IND Collaboration Candidates	3.7.3
Product Claim	10.6.2
Product Infringement	11.3.1
Product License	5.1.2(a)(i)
[***]	[***]
Profit Share Product Exhibit	6.4
Prosecution	11.2.1(b)
Public Official	13.5.4
Purple Book	11.5

Defined Term	Section
Quarterly Net Sales	10.6.3(d)
Receiving Party	12.1
Regulatory Milestone Event	10.4.2
Rejected Candidates	3.7.1
Research Budget	3.3.2
Research Cost Report	10.2.1
Research License	5.1.1
Research Plan	3.3.1
Research Program Information	12.8.1
Research Program Inventions	5.4.2(a)
Research Program Inventions Cross License	5.4.2(a)
Reserved Antigens	3.2.2
[***]	[***]
Right of Reference	8.3.1
Royalty Term	10.6.2
Sales Milestone Event	10.5
Selection Date	3.7.3
Shared Development Costs	Exhibit 6.4
[***]	[***]
Step Down Date	10.6.3(a)
Subcontractor	7.7
Supplemental Application	1.97
Technology Transfer Plan	9.9.2
Term	15.1
[***]	[***]
Third Party Competitive Product	11.3.1
Unadjusted Quarterly Royalties	10.6.3(d)
[***]	[***]
U.S. Commercialization Option	Exhibit 6.4
USJCC	Exhibit 6.4
U.S. Pre-Tax Profits and Losses	Exhibit 6.4
Withholding Tax Action	10.12.2

#### 2.1 Joint Research Committee.

- **2.1.1 JRC Formation; Composition**. The Parties shall establish a joint research committee (the "**JRC**") to oversee and direct the Parties' activities under the Research Programs during the applicable Antigen Research Terms. The Parties shall establish the JRC, and shall use [\*\*\*] Efforts to do so within [\*\*\*] days after the Effective Date. The JRC shall be composed of at least three (3) employee representatives of each Party, each with scientific and technical capabilities to carry out the responsibilities of the JRC and sufficient seniority within the applicable Party to make decisions arising within the scope of the JRC's responsibilities. Each Party may change its JRC representatives from time to time in its sole discretion, effective upon written notice to the other Party of such change. The JRC shall be disbanded after the end of the last Antigen Research Term (except to the extent it needs to be formed again to perform duties relating to improvements under Section 5.6).
- **2.1.2 JRC Responsibilities.** The JRC shall: (a) oversee the implementation of the Research Plans (other than the CMC Development activities in the Research Plans, which shall be subject to the oversight of the JMC as described below in Section 2.2); (b) serve as a forum for and facilitate communications between the Parties with respect to the activities conducted under each Research Plan during the applicable Antigen Research Term (other than the CMC Development activities); (c) prepare, discuss, and approve any amendments to a Research Plan in accordance with Section 3.3.5, other than amendments to the CMC Development activities; (d) prepare, discuss and approve the initial Research Plans for Janssen Antigens 3 and 4 in accordance with Section 3.3.4, other than the CMC Development activities included in such initial Research Plans; (e) select Collaboration Candidates to further develop in IND Enabling Studies in accordance with Section 3.7; (f) approve the IND submission for a Licensed Product in accordance with Section 4.4.3 (other than the CMC portions thereof); and (g) perform the other functions that are expressly delegated to the JRC in this Agreement.
- **2.1.3 JRC Decision Making.** The JRC shall determine, approve or resolve Committee Matters within the authority of the JRC by unanimous vote, with each Party's representatives on the JRC collectively having one (1) vote. If the JRC representatives of the Parties do not reach consensus as to a particular Committee Matter within [\*\*\*] days after such matter is first presented to the JRC, after reasonable discussion and good faith consideration of each Party's comments, then:
  - (a) [\*\*\*]
    (b) [\*\*\*]
    (i) [\*\*\*]
    (ii) [\*\*\*]
    (iii) [\*\*\*]

[\*\*\*].

## 2.2 **Joint Manufacturing Committee.**

**2.2.1 JMC Formation; Composition**. The Parties shall establish a joint manufacturing committee (the "**JMC**"). The Parties shall establish the JMC, and shall use [\*\*\*] Efforts to do so within [\*\*\*] days after the Effective Date. The JMC shall be composed of at least three (3) employee representatives of each Party, each with scientific and technical capabilities to carry out the responsibilities of the JMC and sufficient seniority within the applicable Party to make decisions arising with the scope of the JMC's responsibilities. Each Party may change its JMC representatives from time to time in its sole discretion, effective upon written notice to the other Party of such change.

# 2.2.2 JMC Responsibilities.

(a) During the Antigen Research Term for a Janssen Antigen, the JMC shall: (i) provide high-level oversight of the activities conducted by Fate under the applicable Research Plan pertaining to [\*\*\*] and activities conducted by Fate pertaining to [\*\*\*]; (ii) allocate responsibility for, and oversee the implementation of, the [\*\*\*] in the Research Plan; (iii) serve as a forum for and facilitate communications between the Parties with respect to the CMC Development activities conducted under the Research Plan; (iv) prepare, discuss, and approve any amendments to the CMC Development activities included in the Research Plan in accordance with Section 3.3.5 (including corresponding amendments to the Research Budget), and the CMC Development activities included in the initial Research Plans for Janssen Antigens 3 and 4 in accordance with Section 3.3.4 (including the amounts budgeted for such activities in the applicable Research Budget); (v) approve [\*\*\*] in accordance with Section 4.4.3; and (vi) perform the other functions that are expressly delegated to the JMC during the Antigen Research Term in this Agreement.

(b) If Janssen exercises the Commercial Option for a Collaboration Candidate, the JMC shall: (i) develop and approve a [\*\*\*] in accordance with Section 9.1.2; (ii) allocate responsibility for, and oversee the implementation of, the [\*\*\*]; (iii) serve as a forum for and facilitate communications between the Parties with respect to the CMC Development activities conducted under the CMC Development Plan; (iv) prepare, discuss, and approve any amendments to the CMC Development Plan in accordance with Section 9.1.2; (v) oversee Fate's Manufacture of Early Stage Clinical Supplies of Licensed Products in accordance with Section 9.3; (vi) allocate responsibility for, and oversee the implementation of, [\*\*\*] in accordance with Sections 9.4 and 9.5; and (vii) perform the other functions that are expressly delegated to the JMC in this Agreement.

**2.2.3 JMC Decision Making**. The JMC shall determine, approve or resolve Committee Matters within the authority of the JMC by unanimous vote, with each Party's representatives on the JMC collectively having one (1) vote. If the JMC representatives of the Parties do not reach consensus as to a particular Committee Matter within [\*\*\*] days after such matter is first presented to the JMC, after reasonable discussion and good faith consideration of each Party's comments, then:

- (a) [\*\*\*]
- **(b)** [\*\*\*]
- (c) [\*\*\*]

## 2.3 **Joint Steering Committee.**

- **2.3.1 JSC Formation; Composition**. If Janssen exercises any Commercial Option in accordance with Section 4.3, the Parties shall establish a joint steering committee (the "**JSC**") to discuss and communicate regarding Janssen's global clinical Development and Commercialization of Licensed Products. The Parties shall use [\*\*\*] Efforts to establish the JSC within [\*\*\*] days after Janssen's first exercise of the Commercial Option with respect to any Collaboration Candidate. The JSC shall be composed of at least three (3) senior executives from each Party. Each Party may change its JSC representatives from time to time in its sole discretion, effective upon written notice to the other Party of such change.
- **2.3.2 JSC Responsibilities**. The JSC shall: (a) serve as a forum for discussions regarding Janssen's global Development and Commercialization of the Licensed Products as described in this Agreement; and (b) if Fate exercises any Fate Opt-In Option, have the responsibilities set forth in the Profit Share Product Exhibit.
- **2.3.3 JSC Authority**. Except as provided in the Profit Share Product Exhibit, the JSC shall be a forum for information exchange and discussion only with respect to Licensed Products and has no decision-making authority.
- **Meetings and Minutes.** Each Committee shall hold meetings in accordance with a schedule established by 2.4 mutual written agreement of the Parties, and each Committee shall meet at least once each Calendar Quarter, unless otherwise agreed by the applicable Committee. Each Committee may meet in person or by means of teleconference, Internet conference, videoconference or other similar communications equipment, as agreed to by the Parties; provided, however, that, unless otherwise agreed by the Parties, each Committee shall hold at least two (2) in-person meetings per year, with the location for such in-person meetings alternating (on a Committee-by-Committee basis) between Fate's and Janssen's facilities in the United States, or such other location as may be mutually agreed upon by the members of the relevant Committee. For each Committee, each Party shall designate one of its representatives on such Committee to co-chair the meetings for such Committee (each, a "Co-Chair"). Each Party's Co-Chair may also call for special meetings to resolve particular matters requested by such Party upon [\*\*\*] Business Days' prior written notice to the other Party's applicable Committee members. Each Party shall bear its own expenses related to participation in and attendance at such meetings by its Committee representatives. The Co-Chairs shall, with and through the assistance of the Alliance Managers, coordinate and prepare the agenda for, and ensure the orderly conduct of, the meetings of each Committee. The Co-Chairs shall, with and through the assistance of the Alliance Managers, solicit agenda items from Committee members and provide an agenda, along with appropriate information for such agenda, reasonably in advance of any meeting. Such agenda shall include all items requested by either Co-Chair for inclusion therein. In the event a Co-Chair or another Committee member from either Party is unable to attend or participate in a meeting of a Committee, the Party whose Co-Chair or member is unable to attend may designate a substitute co-chair or other representative for such meeting. Each Party, through its Co-Chair and Alliance Manager, shall alternate responsibility for preparing written minutes of the meetings of each Committee and shall provide such minutes to the Committee members for review no later than [\*\*\*] Business Days after the date of the meeting to which the minutes pertain, which minutes shall become official if the Parties do not provide any comments to such minutes within [\*\*\*] Business Days of its receipt (or such additional period of time as mutually agreed by the Parties) after the Party entrusted with such responsibility at such meeting provides such minutes to the Parties for review. In the event that a Party provides comments to the minutes within such [\*\*\*] Business Day period (or such additional period of time as mutually agreed by the Parties), the Committee members of each Party will discuss such comments in good faith to resolve any discrepancies within [\*\*\*] Business Days after receipt of such comments.

- **2.5 Subcommittees.** From time to time, each Committee may establish subcommittees to perform particular tasks and oversee particular projects or activities within the forming Committee's authority. Each such subcommittee shall be constituted and shall operate as the forming Committee determines, *provided* that no subcommittee shall have any decision-making authority, but shall instead make recommendations to the forming Committee with respect to such matters within its authority.
- **2.6 Limitations of Committee Authority**. Each Committee shall only have authority to determine, approve or resolve matters that such Committee is expressly authorized to determine, approve or resolve under this Agreement ("**Committee Matters**"). No Committee has the authority to: (a) modify or amend the terms and conditions of this Agreement; (b) waive or determine either Party's compliance with the terms and conditions of this Agreement; (c) decide any issue in a manner that would conflict with the express terms and conditions of this Agreement; (d) decide any issue for which this Agreement expressly requires a Party's approval or consent; or (e) resolve any Dispute under this Agreement, including a Dispute as to whether a Committee Matter is subject to Janssen's final decision-making authority or a Dispute related to any payments.
- **2.7 Discontinuation of Committees.** The activities to be performed by each Committee shall solely relate to governance and information sharing under this Agreement, and are not intended to be, or involve the delivery of, services. Each Committee shall continue to exist for so long as this Agreement provides, unless and until the first to occur of: (a) the Parties mutually agreeing to disband the Committee; or (b) Fate providing written notice to Janssen of its intention to disband and no longer participate in such Committee. Once the Parties mutually agree or Fate has provided written notice to disband such Committee, such Committee shall have no further authority or duties under this Agreement. Thereafter, (i) each Party shall designate a contact person for the exchange of information previously exchanged through such Committee, and (ii) any decisions that are designated under this Agreement as being subject to the review or approval of such Committee shall be made by mutual agreement of the Parties directly (other than any matter that was subject to the final decision-making authority of a Party under Section 2.1.3(b) or Section 2.2.3 of this Agreement or Section 2.6.4 of the Profit Share Product Exhibit, which shall be made directly by such Party), subject to the other terms and conditions of this Agreement.
- **2.8 Alliance Managers.** Promptly after the Effective Date, each Party shall appoint an individual to act as the alliance manager for such Party (each, an "**Alliance Manager**"). The Alliance Managers shall not be members of any Committee, but shall be permitted to attend meetings of any Committee as a nonvoting observer. The Alliance Managers shall be the primary point of contact for the Parties regarding their collaboration under this Agreement and shall facilitate communication regarding all activities under this Agreement, including relating to decisions made by the Committees. Each Party may change its designated Alliance Manager from time to time upon notice to the other Party. The name and contact information for each Alliance Manager and any replacement shall be promptly provided to the other Party.

# ARTICLE 3 RESEARCH

- **3.1 Overview**. As further described in this ARTICLE 3 and other provisions of this Agreement:
- **3.1.1** During the Antigen Research Term applicable to each Janssen Antigen, the Parties will collaborate, including through Fate's practice of Fate Platform Technology, to conduct the Research Program for each Janssen Antigen selected by the Parties in accordance with Section 3.2, with the objective of, for each Janssen Antigen, advancing at least one Collaboration Candidate through completion of IND Enabling Studies.
- **3.1.2** For each Janssen Antigen, there will be a single Research Plan, where such Research Plan may incorporate multiple Collaboration Candidates, including Collaboration Candidates that are CAR-NK Cells, CAR-T Cells or both. If the Parties update a Research Plan to incorporate activities for a Next Generation Candidate in accordance with Section 5.6, such activities shall become part of the original Research Program for the applicable Janssen Antigen.
- **3.1.3** For each Research Program, Janssen will designate and provide no more than [\*\*\*] Janssen Antigen Binding Domains to Fate for the purpose of generating Collaboration Candidates incorporating such Janssen Antigen Binding Domain. Janssen may provide a Janssen Antigen Binding Domain to Fate either by providing tangible materials containing the binding domain or by disclosing the amino acid sequence of the binding domain. References in this Agreement to "Janssen Antigen Binding Domains with respect to a Janssen Antigen" means all Janssen Antigen Binding Domains designated and provided to Fate by Janssen for the particular Research Program, even if none of the resulting Collaboration Candidates contain such Janssen Antigen Binding Domain. [\*\*\*].
  - **3.2 Janssen Antigens**. There shall be at least two (2) and up to four (4) Janssen Antigens, selected as follows:
- **3.2.1 Janssen Antigens 1 and Janssen Antigen 2**. As of the Effective Date, the Parties have agreed on the initial two (2) Janssen Antigens: [\*\*\*] is referred to as "**Janssen Antigen 1**" and [\*\*\*] is referred to as "**Janssen Antigen 2**". The Parties acknowledge that the initial objective of the Research Plan for Janssen Antigen 1 is to Research Collaboration Candidates that could treat [\*\*\*], and the initial objective of the Research Plan for Janssen Antigen 2 is to Research Collaboration Candidates that could treat [\*\*\*]. These initial objectives do not limit the potential scope of the Research Plan, and do not create a field limitation on any of the licenses granted to Janssen under ARTICLE 5.

3.2.2 Janssen Antigen 3 and Janssen Antigen 4. As of the Effective Date, the Parties have identified the [\*\*\*] antigens listed on Exhibit 3.2.2 as the antigens that are reserved for selection by Janssen under this Agreement (the "Reserved Antigens"). Within [\*\*\*] months after the Effective Date (the "Antigen Selection Period"), Janssen may select any Reserved Antigen as "Janssen Antigen 3" and as "Janssen Antigen 4" by giving written notice to Fate, [\*\*\*]. If Janssen has not selected both Janssen Antigen 3 and Janssen Antigen 4 prior to the expiration of the Antigen Selection Period, Janssen will have the right to extend such Antigen Selection Period by an additional [\*\*\*] months by giving written notice to Fate; provided, however, that such [\*\*\*]-month extension will be effective only if Janssen removes [\*\*\*] Reserved Antigens from Exhibit 3.2.2 at the time of such extension (in which case such removed Reserved Antigens will no longer be Reserved Antigens and shall be removed from Exhibit 3.2.2). For clarity, Janssen may select Janssen Antigen 3 and Janssen Antigen 4 at different times during such period (and, upon each such selection, such selected Reserved Antigen will be a Janssen Antigen and will no longer be a Reserved Antigen and shall be removed from Exhibit 3.2.2). Fate will not enter into an agreement with a Third Party relating to, or grant any rights to any Third Party with respect to, any CAR-T Cells or CAR-NK Cells expressing a CAR Directed to any antigen that is then-currently a Reserved Antigen. For clarity, upon expiration of such Antigen Selection Period (or, if extended, such additional [\*\*\*] month period) after the Effective Date, all Reserved Antigens on Exhibit 3.2.2 will promptly be removed from Exhibit 3.2.2 and no antigens will be Reserved Antigens under this Agreement.

**3.2.3 Replacement of Janssen Antigen 2 and Substitution of Reserved Antigens.** Janssen may replace Janssen 7 Antigen 2 with a Reserved Antigen, or substitute any Reserved Antigen with another antigen, in each case subject to the following provisions of this Section 3.2.3.

- (a) [\*\*\*].
- (b) [\*\*\*].

(c) As of the Effective Date, the antigen [\*\*\*] is not included as a Reserved Antigen on Exhibit 3.2.2 because [\*\*\*]. If such antigen becomes available during the Antigen Selection Period, Fate shall promptly notify Janssen. Janssen may substitute a Reserved Antigen with such antigen by written notice to Fate within [\*\*\*] days of such notice from Fate. Such substitution shall not be subject to Fate's prior written approval. After any such substitution, such antigen will be a Reserved Antigen and such original Reserved Antigen shall no longer be a Reserved Antigen and shall be removed from Exhibit 3.2.2.

#### 3.3 Research Plans.

- **3.3.1 Content.** The Parties shall conduct each Research Program for each Janssen Antigen during the Antigen Research Term pursuant to a comprehensive written research plan (each, a "**Research Plan**").
- (a) The objective of each Research Program shall be to identify, develop and optimize Collaboration Candidate(s), and to further develop at least one (1) such Collaboration Candidate in IND Enabling Studies and, if Janssen exercises a Commercial Option for such Collaboration Candidate in accordance with Section 4.3, submit an IND for at least one (1) Licensed Product. The Research Plan for a Research Program shall set forth: (i) all activities to be conducted by each of the Parties with the aim to achieve such objective, including the activities described in **Exhibit 3.3.3**, and an allocation of activities between the Parties that is consistent with **Exhibit 3.3.3**; (ii) the resources to be allocated to and the anticipated number and type of FTEs to be dedicated to performing each of such activities; (iii) the projected timeline for completing, and milestone events to be achieved for, such activities; (iv) the criteria for evaluating and selecting Collaboration Candidates when determining which ones will be further developed in IND Enabling Studies (the "**IND Selection Criteria**"); (v) a description of the DC Data Package for such Research Program; and (vi) a description of the IND Data Package for such Research Program.
- **(b) Data Packages**. For each Research Program with respect to a Janssen Antigen, the Research Plan shall describe the contents of the DC Data Package and IND Data Package for such Research Program.
- **3.3.2 Research Budget.** Each Research Plan shall include a rolling, [\*\*\*] year budget for Research Costs to be incurred by each Party and its Affiliates in conducting the activities described in the Research Plan that are scheduled to be commenced or conducted during the [\*\*\*] (with respect to such Calendar Years, the "**Research Budget**"). The Research Budget shall be broken down by Calendar Quarter and, for each Calendar Quarter, shall be broken down by Research FTE Costs and Out-of-Pocket Expenses. The [\*\*\*] of each Research Budget shall be [\*\*\*], and the [\*\*\*] shall serve as [\*\*\*].

# 3.3.3 Responsibilities of the Parties.

- (a) Janssen shall generate and provide to Fate the Janssen Antigen Binding Domains for use in each Research Program.
- **(b)** Descriptions of the key steps and activities that will be taken to generate Collaboration Candidates of a particular CAR Cell Type Directed to the applicable Janssen Antigen under each Research Plan are set forth on **Exhibit 3.3.3**. Unless the JRC determines otherwise, each Party will have the responsibilities under each Research Program that are set forth on **Exhibit 3.3.3**.
- (c) At the request of either Party, the JRC will also consider and determine whether Janssen should conduct itself or transfer assays, models and materials to Fate that are useful for Fate to conduct its Research Plan activities.

#### 3.3.4 Initial Research Plans; Janssen Antigens 3 and 4 Research Plans.

(a) As of the Effective Date, the Parties have agreed on the initial Research Plans for Janssen Antigen 1 and Janssen Antigen 2, which are attached hereto as **Exhibit 3.3.4**.

(b) Within [\*\*\*] days of the selection of each of Janssen Antigen 3 and Janssen Antigen 4 by Janssen pursuant to Section 3.2.2, the JRC shall prepare, discuss, and approve the Research Plan (including the Research Budget) for such Janssen Antigen, subject to the JMC's responsibility for the portions relating to CMC Development activities as described in Section 3.3.5(d). Such Research Plan shall be, in form and substance (including with respect to the activities to be conducted thereunder and the number of FTEs needed to conduct such activities), substantially similar to the form and substance of the Research Plans for Janssen Antigen 1 and Janssen Antigen 2.

(c) In the event that the JRC does not reach consensus on the Research Budget for the initial Research Plan for Janssen Antigen 3 or Janssen Antigen 4 within such [\*\*\*]-day period, then such Research Budget shall equal [\*\*\*]; provided, however, that in no event shall a Research Plan require Fate to conduct activities that, taken as a whole, would result in Fate incurring Research Costs in excess of the applicable Research Budget for such Research Plan. The Research Plans for Janssen Antigen 3 and Janssen Antigen 4 shall, when practicable, stage activities based on the data, results and information generated from the Research Programs for Janssen Antigen 1 and Janssen Antigen 2.

#### 3.3.5 Updates and Amendments.

(a) The JRC shall regularly review the Research Plans and the progress of activities being conducted under the Research Plans, subject to the JMC's responsibility for the portions relating to CMC Development activities as described in Section 3.3.5(d). During the Antigen Research Term for each Janssen Antigen, the JRC and the JMC (with respect to CMC Development activities) shall review the applicable Research Plan annually and prepare any recommended updates. No later than [\*\*\*] of the then-current Calendar Year, the JRC shall prepare an updated Research Budget covering the next [\*\*\*]. After each Party performs its internal budgeting process, the JRC shall use reasonable efforts to approve such updates no later than [\*\*\*] of each Calendar Year.

(b) Either Party may propose amendments to the Research Plan, including the Research Budget, for any Janssen Antigen from time to time, including (i) amendments that take into account completion, commencement, or cessation of activities contemplated in the then-current Research Plan for, or any newly available information related to, the Janssen Antigen or the Research Program and (ii) amendments that would include Research of a Collaboration Candidate of a different CAR Cell Type for any Janssen Antigen under the Research Program. The JRC shall discuss whether to approve such proposal at its next meeting, subject to the JMC's responsibility for the portions relating to CMC Development activities as described in Section 3.3.5(d).

- (c) Such updates and amendments shall be effective upon JRC approval, subject to the JMC's responsibility for the portions relating to CMC Development activities as described in Section 3.3.5(d).
  - **(d)** The JMC will have authority for [\*\*\*].

#### 3.4 Research Term Extension.

**3.4.1 Extension for Ongoing Activities.** In the event there are any activities under the then-current Research Plan with respect to a particular Janssen Antigen that have not been completed before the expiration of the Initial Research Term, the Antigen Research Term for such Janssen Antigen shall be extended automatically until such activities are completed; *provided*, *however*, that the Research Plan shall not be modified or amended during such extension period without the Parties' mutual written agreement.

# 3.4.2 Extension or Reinstatement for Functional Improvements.

- (a) If, during the Antigen Research Term, the JRC updates or the Parties update the Research Plan for a Janssen Antigen pursuant to Section 5.6 to include activities for a Next Generation Candidate Directed to such Janssen Antigen, the Antigen Research Term will be extended automatically with respect to such Janssen Antigen to take into account such update.
- (b) If, during the Improvement Period with respect to a Licensed Product, the JRC updates or the Parties update the Research Plan for the Janssen Antigen that is targeted by such Licensed Product pursuant to Section 5.6 to include activities for a Next Generation Candidate Directed to such Janssen Antigen, the Antigen Research Term will be reinstated with respect to such Janssen Antigen solely as necessary to conduct such activities, and such reinstated Antigen Research Term shall commence on the date the JRC updates such Research Plan and end when the applicable activities are completed.
- **3.5 Conduct of Research.** Each Party shall use [\*\*\*] Efforts to carry out the activities assigned to it in the Research Plans in accordance with the timelines set forth in such plans. Each Party shall conduct such activities in good scientific manner, and in compliance with all applicable Laws. Each Party shall keep the other Party reasonably informed as to the progress of the conduct of the Research Plans through meetings of the JRC.
- **3.6 Research Cost.** Janssen shall be responsible for one hundred percent (100%) of the costs and expenses incurred by Janssen in performing the Research Plans. Janssen shall reimburse Fate for Research Costs incurred by or on account of Fate in performing the Research Plans pursuant to Section 10.2.

#### 3.7 IND Enabling Studies.

- 3.7.1 For each Research Plan, after Fate completes the activities described in Step 5 in Exhibit 3.3.3, Fate shall promptly prepare and deliver to Janssen a complete DC Data Package for the Collaboration Candidates that the JRC is considering for further development (such Collaboration Candidates, the "DC Collaboration Candidates"). The "DC Data Package" means a collection of all then-available information, data, and results arising from the completion of such activities by Fate for such DC Collaboration Candidates so that a determination may be made as to whether any of such DC Collaboration Candidates should be further developed in IND Enabling Studies. Any cells (including Collaboration Candidates) that are generated in the course of generating the DC Collaboration Candidates included in a particular DC Data Package, but not included in such DC Data Package, will be deemed to be "Rejected Candidates."
- **3.7.2** If Fate delivers a DC Data Package and Janssen notifies Fate within [\*\*\*] days following receipt that such DC Data Package is not complete, and such notice specifies the information, data or results described in the applicable Research Plan with respect to such Collaboration Candidates that was intended to be included and was not included in such DC Data Package, Fate shall generate or provide the missing information, data or results as soon as possible; *provided*, *however*, that Fate shall not be required to generate or provide any information, data, or results beyond those specified in the applicable Research Plan.
- 3.7.3 After the complete DC Data Package is delivered, the JRC shall determine within [\*\*\*] days (as such period may be extended by the JRC) whether any of the applicable DC Collaboration Candidates should be further developed in IND Enabling Studies; provided, however, if the JRC does not reach consensus on such matter during such period, then such period shall be extended by an additional [\*\*\*] Business Days to [\*\*\*] to further develop any such DC Collaboration Candidate(s) in IND Enabling Studies shall be deemed the "Selection Date" for such DC Collaboration Candidate(s), and such DC Collaboration Candidate(s) shall be deemed to be "Pre-IND Collaboration Candidates." With respect to any such DC Collaboration Candidates that are not selected for further development as a Pre-IND Collaboration Candidate, the JRC will determine whether to maintain such DC Collaboration Candidates (to the extent feasible) or whether to destroy such DC Collaboration Candidates; provided, however, that in no event will Fate be required to maintain any DC Collaboration Candidates for more than [\*\*\*] days. A DC Collaboration Candidate will be deemed to be a Discontinued Collaboration Candidate, and will become subject to Section 3.7.6, upon the earlier of: (i) the date on which the JRC decides to destroy such candidate, (ii) the date on which Fate destroys such candidate in accordance with the immediately preceding sentence or (iii) the last day of the Antigen Research Term for the applicable Janssen Antigen if such candidate has not been selected for further development as a Pre-IND Collaboration Candidate before such day. For clarity, the JRC may select (or, if the JRC does not reach consensus, Janssen may select by exercising its final decision-making authority under Section 2.1.3) a DC Collaboration Candidate as a Pre-IND Collaboration Candidate even if such DC Collaboration Candidate does not satisfy the IND Selection Criteria.

- **3.7.4** Following the Selection Date, the JRC shall update the Research Plan as necessary to set forth the specific IND Enabling Studies for the Pre-IND Collaboration Candidate(s) and related activities to be conducted. If the JRC or Janssen has not previously selected a Collaboration Candidate as a Pre-IND Collaboration Candidate with respect to the applicable Janssen Antigen, Janssen shall pay to Fate a milestone fee in accordance with Section 10.2.3. Each Party shall then perform such additional activities allocated to it under the applicable Research Plan with respect to such IND Enabling Studies for each Pre-IND Collaboration Candidate.
- **3.7.5** Any Pre-IND Collaboration Candidate for which Janssen does not exercise its Commercial Option during the applicable Commercial Option Term shall be deemed a Discontinued Collaboration Candidate in accordance with Section 4.3.2 or 4.6, as applicable.
- 3.7.6 Fate shall destroy any Rejected Candidates, and Fate and Janssen shall destroy any Discontinued Collaboration Candidates, including, in each case, all Precursor iPSCs and CD34 Compositions thereof, in the ordinary course. Neither Party will maintain or use any tangible materials regarding any Rejected Candidates or Discontinued Collaboration Candidates unless otherwise agreed by the Parties in writing. Any information or data generated with respect to the Rejected Candidates and Discontinued Collaboration Candidates shall be subject to the license under Section 5.4.1. Given the nature of the Rejected Candidates and Discontinued Collaboration Candidates, and the competitive damage that may result to a Party upon unauthorized maintenance or use of the Rejected Candidates or Discontinued Collaboration Candidates, the Parties agree that monetary damages may not be a sufficient remedy for any breach of this Section 3.7.6. In addition to all other remedies, each Party shall be entitled to seek specific performance and injunctive and other equitable relief as a remedy for any breach or threatened breach of this Section 3.7.6 by the other Party.

#### 3.8 Records; Reports.

- **3.8.1 Records**. Fate (and Janssen, to the extent any activities are assigned to Janssen under a Research Plan) shall maintain, consistent with its then-current internal policies and practices, and cause its employees and Subcontractors to maintain, records and laboratory notebooks of its activities under each Research Plan for each Janssen Antigen in sufficient detail and in a good scientific manner appropriate for regulatory and intellectual property protection purposes. If requested by Janssen, Fate shall provide Janssen with a copy of any such records of Fate, except that Fate may redact any portion of such records that relate to any Fate Confidential Methods.
- **3.8.2 Reports.** Fate (and Janssen, to the extent any activities are assigned to Janssen under a Research Plan) shall report to Janssen (or Fate, if applicable) through the JRC its results in conducting activities under the Research Plan for each Janssen Antigen. For each Research Program, Fate shall provide the JRC with the deliverables set forth in the Research Plan for such Research Program, including summaries of the information, data and results generated under each Research Program, in accordance with any timelines set forth in the Research Plan, and if reasonably requested by Janssen any raw data relating to such activities. In no event will Fate be required to provide Janssen or the JRC any information, data, or results that Fate reasonably determines to be any Fate Confidential Methods.

- 3.9 Subcontracting. Each Party may fulfill its obligations under the Research Plan through subcontracting to a Third Party contractor or contract service organization; *provided*, *however*, that: (a) such Party obtains the other Party's prior written consent to subcontract the applicable activities to the applicable Third Party, not to be unreasonably withheld or delayed; (b) such subcontracting shall not adversely affect its ability to fulfill its obligations under this Agreement or the other Party's rights under this Agreement; (c) any such Third Party contractor to whom a Party discloses Confidential Information of the other Party shall enter into an appropriate written agreement obligating such Third Party contractor to be bound by obligations of confidentiality and restrictions on use of such Confidential Information that are no less restrictive than the obligations in ARTICLE 12; (d) the Party engaging such Third Party will obligate such Third Party contractor to agree in writing to assign or license (with the right to grant sublicenses) to such Party any inventions (and Patents covering such inventions) made by such Third Party contractor in performing such subcontracted activities; and (e) the Party engaging such subcontractor shall at all times be responsible for the performance of such Third Party contractor and shall remain primarily responsible for the fulfillment of its obligations under this Agreement even after such obligations are subcontracted to such Third Party contractor.
- **3.10 Materials**. To facilitate the performance of activities under the Research Programs, either Party may provide to the other Party certain biological materials or chemical compounds owned by or licensed to the supplying Party for use by the other Party (such materials or compounds and any progeny, collectively, "**Materials**"). All such Materials shall remain the sole property of the supplying Party, shall be used by the receiving Party solely to perform its obligations under the Research Programs, shall not be used or delivered to or for the benefit of any Third Party without the prior written consent of the supplying Party, and shall not be used in research or testing involving human subjects, unless expressly agreed. The Materials supplied under this Section are supplied "as is" and must be used with prudence and appropriate caution in any experimental work, since not all of their characteristics may be known.
- **3.11 Potential** [\*\*\*]. In addition to the Research Programs to be conducted pursuant to this Agreement, during the period commencing on the Effective Date and ending on [\*\*\*], the Parties will discuss whether to enter into an agreement for [\*\*\*]. During such period, Fate will not grant any rights to any commercial Third Party with respect to [\*\*\*]. Without limiting the foregoing, during such period, Fate will be permitted to conduct (i) internal research and development, including clinical development and Clinical Trials, of [\*\*\*], and (ii) sponsored research with academic investigators for the research and development, including clinical development and Clinical Trials (but not commercialization), of [\*\*\*].

# ARTICLE 4 Commercial Option

**4.1 Commercial Option.** Fate hereby grants to Janssen an exclusive option to obtain the Commercial License under Section 5.1.2 and Section 5.1.3 for each Pre-IND Collaboration Candidate exercisable in accordance with Section 4.3 (each, a "**Commercial Option**"). Janssen shall not have the right to, and shall not, Develop (except pursuant to the Research License), Manufacture or Commercialize any Collaboration Candidate, or any product containing such Collaboration Candidate, other than those Pre-IND Collaboration Candidates for which Janssen exercises the Commercial Option with respect to such Pre-IND Collaboration Candidate pursuant to Section 4.3.

### 4.2 Delivery of IND Data Packages; Preparation of Master iPSC Bank.

- **4.2.1** With respect to each Pre-IND Collaboration Candidate, Fate shall promptly prepare and deliver to Janssen a complete IND Data Package within [\*\*\*] days following the completion of all IND Enabling Studies for such Pre-IND Collaboration Candidate set forth in the Research Plan. The "**IND Data Package**" means a collection of all then-available information, data, and results from IND Enabling Studies for such Pre-IND Collaboration Candidate. Fate will include in the IND Data Package evidence of the early phase CMC Development process for such Pre-IND Collaboration Candidate, with data demonstrating process manufacturability for future adaption into the pivotal and commercial Manufacturing process.
- **4.2.2** If Fate delivers an IND Data Package and Janssen notifies Fate within [\*\*\*] days following receipt that such IND Data Package is not complete, and such notice specifies the information, data or results described in the applicable Research Plan that was intended to be included and was not included in such IND Data Package, Fate shall generate or provide the missing information, data and results as soon as possible; *provided*, *however*, that Fate shall not be required to generate or provide any information, data, or results beyond those specified in the applicable Research Plan. The date on which Janssen is in receipt of an IND Data Package for a Pre-IND Collaboration Candidate (together with any such missing information as set forth above) shall be deemed the "**IND Data Package Delivery Date**" with respect to such Collaboration Candidate.
- 4.2.3 Fate shall also make available such other information relating to such Pre-IND Collaboration Candidate as Janssen may reasonably request in order to make an informed decision regarding whether to exercise its Commercial Option with respect to such Pre-IND Collaboration Candidate; *provided*, *however*, that Janssen shall not have a right to require that Fate (i) provide any information, data, or results arising outside the scope of the Research Plan or that relates to the Fate Confidential Methods, (ii) perform any further activities with respect to such Pre-IND Collaboration Candidate that are not set forth in the Research Plan, or (iii) generate or prepare information, data or results that would require Fate to incur material additional expenditures (unless such activity is set forth in the Research Plan). Janssen shall make its request, if any, for such additional information, data or results within [\*\*\*] days after the receipt of the applicable IND Data Package, and Fate shall provide such additional information, data and results to Janssen no later than [\*\*\*] days after Janssen's request.

**4.2.4** With respect to each Pre-IND Collaboration Candidate, promptly following the completion of all IND Enabling Studies for such Pre-IND Collaboration Candidate set forth in the Research Plan, Fate shall prepare, test, qualify and release a cryopreserved Master iPSC Bank for such Pre-IND Collaboration Candidate for commencement of IND-enabling pilot manufacture of such Pre-IND Collaboration Candidate by Fate under this Agreement, and shall notify Janssen in writing upon completion of such activities.

### 4.3 Option Exercise.

# 4.3.1 Option Exercise.

Collaboration Candidate, it may do so at any time during the applicable Commercial Option Term by giving Fate written notice of exercise specifying the applicable Pre-IND Collaboration Candidate (the "Exercise Notice" and, subject to Section 4.3.2, the first Business Day after Fate's receipt of such notice, the "Exercise Effective Date"). Each Pre-IND Collaboration Candidate as to which Janssen has exercised a Commercial Option during the applicable Commercial Option Term shall automatically be a Licensed Collaboration Candidate upon the Exercise Effective Date, subject to Section 4.3.2. For clarity, the Commercial Option is exercisable on a Pre-IND Collaboration Candidate-by-Pre-IND Collaboration Candidate basis during the applicable Commercial Option Term for each such Pre-IND Collaboration Candidate. Within [\*\*\*] days after the Exercise Effective Date, Fate will deliver to Janssen non-disturbance agreements (in a form mutually acceptable to the Parties) executed by each secured lender of record of Fate that holds a senior security interest in any of the intellectual property subject to the Commercial License (if any), consenting to the Commercial License and agreeing not to disturb Janssen's interest in such intellectual property in the event of foreclosure of such security interest for so long as Janssen is in compliance with the terms and conditions of this Agreement.

**(b)** "Commercial Option Term" means, with respect to a Pre-IND Collaboration Candidate, the time period [\*\*\*] (the "Commercial Option Start Date"), and (z) ending on the date that is [\*\*\*] days after the Commercial Option Start Date for such Collaboration Candidate[\*\*\*]. Notwithstanding the foregoing, if Janssen is stayed from exercising its Commercial Option for a Pre-IND Collaboration Candidate during such [\*\*\*] day period by the filing of a petition by Fate under the Bankruptcy Code or otherwise under the Bankruptcy Code, the Commercial Option Term for such Pre-IND Collaboration Candidate shall not end before the date that is [\*\*\*] days after the lifting or expiration of such stay.

- Clearance Date. Notwithstanding the foregoing, if Janssen determines a filing or submission 4.3.2 with respect to the exercise of a Commercial Option under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (the "HSR Act") or any antitrust, competition or merger control Law applicable to such exercise (collectively, "Competition Laws" and, such filing or submission, "Competition Law Filings") is required or advisable, Janssen shall provide, prior to or concurrently with its exercise of the Commercial Option pursuant to Section 4.3.1, written notice to Fate that the exercise of the Commercial Option will be subject to Competition Law Filings. If Janssen so notifies Fate, the provisions of Section 17.12 shall apply. Fate shall provide to Janssen any information reasonably requested by Janssen in its assessment of potential notifications under applicable Competition Laws pursuant to this Section 4.3.2. In such event, the applicable Commercial Option Term will automatically be tolled until the Clearance Date, and the Exercise Effective Date will be deemed to be the date that is the Clearance Date. Following the earlier occurrence of: (i) the FTC or DOJ obtains a preliminary injunction against the Parties to enjoin the transactions contemplated by the applicable Exercise Notice or (ii) the Clearance Date does not occur within [\*\*\*] days after the Competition Law Filing, Janssen shall have the right, but not the obligation, to withdraw the applicable Exercise Notice by delivery of written notice to Fate. Immediately upon such a withdrawal, the applicable Exercise Notice shall become null and void and have no further force or effect, the Commercial Option Term shall expire and the applicable Pre-IND Collaboration Candidate shall be deemed to be a Discontinued Collaboration Candidate.
- **4.4 Effect of Option Exercise.** If Janssen exercises the Commercial Option with respect to a particular Pre-IND Collaboration Candidate in accordance with Section 4.3, then upon and after the occurrence of the Exercise Effective Date, the following provisions of this Section 4.4 shall apply.
- **4.4.1 Commercial License.** Such particular Pre-IND Collaboration Candidate will be deemed a Licensed Collaboration Candidate, and the Commercial License granted to Janssen under Section 5.1.2 shall apply to such Licensed Collaboration Candidate and the corresponding Licensed Products.
- **4.4.2 Option Exercise Payment**. If Janssen has not previously exercised the Commercial Option for any other Pre-IND Collaboration Candidate with respect to the applicable Janssen Antigen, Janssen shall pay to Fate the Option Exercise Payment in accordance with Section 10.2.4.
- **4.4.3 IND Filing.** The Parties shall, in accordance with the applicable Research Plan, commence the preparation of an IND application for a Licensed Product for the applicable Licensed Collaboration Candidate. If, at the time of the Exercise Effective Date for the Licensed Collaboration Candidate, there are IND Enabling Studies being conducted for other Pre-IND Collaboration Candidates that were included in the same DC Data Package as the Licensed Collaboration Candidate, Janssen may elect [\*\*\*] Janssen will decide whether to exercise the Commercial Option for any of such other Pre-IND Collaboration Candidate in accordance with Section 4.3 and for which of such candidates IND applications should be prepared. Janssen shall make the IND application decision no later than [\*\*\*] days after the IND Data Package Delivery Date for [\*\*\*]. Fate shall be primarily responsible for the preparation of the IND application for such Licensed Product, except that Janssen shall prepare the clinical trial protocol. Fate shall provide the IND application to Janssen for review and comment, and to the JRC for review and approval (and to the JMC for review and approval of the CMC portions of such application), prior to submitting such application to the FDA. Following JRC and JMC approval, Fate shall promptly submit such IND application to the FDA for such Licensed Product. If Janssen notifies Fate that it intends to conduct the first Clinical Trial in a country outside the U.S., the Parties will discuss and agree upon responsibility for preparation and submission of the CTA to the applicable Regulatory Authority in such country.

- **4.4.4 Development Technology Transfer**. During the remainder of the Term with respect to the applicable Licensed Collaboration Candidate, Fate shall reasonably cooperate with Janssen to provide reasonable technical assistance, including the transfer to Janssen of any Fate Product Know-How licensed to Janssen under Section 5.1.2(a)(i) with respect to such Licensed Collaboration Candidate, as reasonably necessary for Janssen to Develop [\*\*\*], but not to Manufacture, such Licensed Collaboration Candidate and Licensed Products containing such Licensed Collaboration Candidate; *provided, however*, that any transfer, use and disclosure of any Fate Confidential Methods shall be limited to those set forth under Section 5.3 and subject to Section 5.3. Fate's cooperation under this Section 4.4.4 may be carried out by providing Janssen with reasonable access by teleconference or, during the first [\*\*\*] months after the Exercise Effective Date, in-person at Fate's facilities to those Fate personnel knowledgeable with respect to Development of such Licensed Collaboration Candidate and Licensed Products containing such Licensed Collaboration Candidate, but such teleconference or in-person assistance shall not extend beyond the scope of technology transfer as set forth above.
- **4.4.5 License to Discontinued Collaboration Candidates and Equivalents.** The license granted to Janssen under Section 5.1.3 shall also apply to: (a) Discontinued Collaboration Candidates of the same CAR Cell Type under the same Research Program as the Licensed Collaboration Candidate; and (b) Equivalents of (i) the Licensed Collaboration Candidate, (ii) the Discontinued Collaboration Candidates described in clause (a) and (iii) any Licensed Product containing either the Licensed Collaboration Candidate or Discontinued Collaboration Candidates described in clause (a).
- **4.5 Ongoing Activities.** If there is more than one (1) Pre-IND Collaboration Candidate for which IND Enabling Studies are being conducted under the Research Plan for a Janssen Antigen, Janssen's exercise of the Commercial Option (or the expiration of the Commercial Option Term) with respect to one of such Pre-IND Collaboration Candidates will not terminate or modify the work under such Research Plan for other Collaboration Candidate(s) of the same CAR Cell Type, unless the Parties otherwise agree. In addition, if a Research Program includes Research for both CAR-NK Cells and CAR-T Cells, Janssen's exercise of the Commercial Option (or the expiration of the Commercial Option Term) with respect to any Collaboration Candidate for one CAR Cell Type will not terminate or modify the work under such Research Plan for Collaboration Candidates of the other CAR Cell Type, unless the Parties otherwise agree.
- **4.6 Non-Exercise of Option**. If Janssen fails to give the Exercise Notice on or before the expiration of the applicable Commercial Option Term for a Pre-IND Collaboration Candidate or notifies Fate in writing prior to the expiration of the applicable Commercial Option Term that Janssen will not be exercising its Commercial Option for such Pre-IND Collaboration Candidate, then the Commercial Option with respect to such Pre-IND Collaboration Candidate shall expire upon the earlier of the expiration of the Commercial Option Term or the delivery of such notice, and Section 5.10.2(a) shall apply thereafter with respect to such Pre-IND Collaboration Candidate. Such Pre-IND Collaboration Candidate shall thereupon be deemed a Discontinued Collaboration Candidate.

# ARTICLE 5 GRANT OF RIGHTS; EXCLUSIVITY

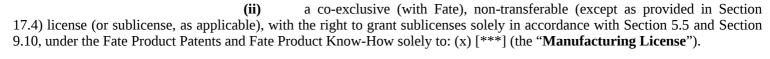
#### 5.1 Licenses To Janssen.

Research License. Subject to the terms and conditions of this Agreement, during the Antigen Research Term for each Janssen Antigen, Fate hereby grants to Janssen a non-exclusive, royalty-free, non-transferable (except as permitted under Section 17.4) license in the Territory, with the right to grant sublicenses solely in accordance with Section 5.5.1, under Fate Research Patents and Fate Research Know-How solely as and to the extent necessary to enable Janssen to perform Janssen's obligations as set forth under the Research Plan for each Janssen Antigen (including through the engagement of subcontractors in accordance with Section 3.9) (the "Research License"). For the avoidance of doubt, (a) except as otherwise expressly set forth in the Research Plan for the Janssen Antigen, Janssen shall not conduct any Development, Manufacture, or Commercialization of any Collaboration Candidate, or any product containing any Collaboration Candidate, unless and until such time as Janssen exercises its Commercial Option in accordance with Section 4.3 for such Collaboration Candidate and such Collaboration Candidate becomes a Licensed Collaboration Candidate, (b) if Janssen does not exercise its Commercial Option with respect to a Collaboration Candidate during the applicable Commercial Option Term in accordance with Section 4.3, the Research License granted to Janssen under this Section 5.1.1 shall expire with respect to such Collaboration Candidate upon expiration of such Commercial Option Term; and (c) if Janssen terminates this Agreement under Section 15.3 with respect to any particular Janssen Antigen during the Antigen Research Term, then the Research License granted to Janssen under this Section 5.1.1 with respect to such Janssen Antigen shall terminate in accordance with Section 15.7.1(a) and this Agreement shall terminate with respect to such Janssen Antigen in accordance with Section 15.3. During the Antigen Research Term for each Janssen Antigen, Fate shall not enter into an agreement with a Third Party relating to, or otherwise grant any rights to any Third Party with respect to, any CAR Cell Construct expressing a CAR Directed to such Janssen Antigen.

#### 5.1.2 Commercial License.

(a) Subject to the terms and conditions of this Agreement (including ARTICLE 9), upon and as of the Exercise Effective Date for a Licensed Collaboration Candidate and for the remainder of the Term with respect to such Licensed Collaboration Candidate, Fate hereby grants to Janssen:

(i) an exclusive (even as to Fate, except solely to the extent necessary for Fate to exercise its rights and perform its obligations under this Agreement), non-transferable (except as provided in Section 17.4), royalty-bearing license (or sublicense, as applicable), with the right to grant sublicenses solely in accordance with Section 5.5, under the Fate Product Patents and Fate Product Know-How solely to: (x) use, Develop, have Developed, sell, offer to sell, have sold, promote, distribute, import, export and otherwise Commercialize such Licensed Collaboration Candidate and Licensed Products containing such Licensed Collaboration Candidate in the Field in the Territory and (y) [\*\*\*] (the "**Product License**"); and



- **(b)** The Product License and Manufacturing License shall collectively be deemed the "**Commercial License**" with respect to the applicable Licensed Collaboration Candidate and Licensed Products containing such Licensed Collaboration Candidate.
- **5.1.3 License to Discontinued Collaboration Candidates and Equivalents.** Subject to the terms and conditions of this Agreement, upon and as of the Exercise Effective Date for a Licensed Collaboration Candidate and effective only for the remainder of the Term with respect to such Licensed Collaboration Candidate, Fate hereby also grants to Janssen a Commercial License with respect to:
- (a) All Discontinued Collaboration Candidates, then existing or becoming a Discontinued Collaboration Candidate by operation of this Agreement subsequently, of the same CAR Cell Type under the same Research Program as such Licensed Collaboration Candidate; and
- **(b)** Equivalents of (i) such Licensed Collaboration Candidate, (ii) the Discontinued Collaboration Candidates described in clause (a) of this Section 5.1.3 and (iii) any Licensed Product containing either such Licensed Collaboration Candidate or any Discontinued Collaboration Candidate described in clause (a) of this Section 5.1.3.

Notwithstanding the foregoing, Janssen shall not have the right to practice the Commercial License described in Section 5.1.2 for any product described in clause (a) or (b) of this Section 5.1.3 without mutual agreement of the Parties, and *provided* that Janssen may not practice such license unless and until Fate prepares, tests, qualifies and releases a cryopreserved Master iPSC Bank for the applicable Discontinued Collaboration Candidate or Equivalent in accordance with Section 4.2.4. If the Parties mutually agree that Janssen may practice the Commercial License for such product, then the applicable Discontinued Collaboration Candidate or Equivalent shall be deemed to be a Licensed Collaboration Candidate for all purposes under this Agreement.

# 5.1.4 Limitation of License; Retained Right of Fate.

(a) For clarity, (i) the licenses granted to Janssen under this Section 5.1 do not include the right for Janssen to practice the Fate Research Patents, Fate Research Know-How, Fate Product Patents or Fate Product Know-How in a manner other than as expressly permitted under this Section 5.1 or Section 5.4 or ARTICLE 9; and (ii) Fate retains all rights to practice the Fate Research Patents, Fate Research Know-How, Fate Product Patents or Fate Product Know-How for any and all purposes, other than those expressly limited by license under Section 5.1, subject only to Section 5.1.4(b) and Section 5.10.

Banks, or CD34 Compositions corresponding to a Licensed Collaboration Candidate for any purpose other than the performance of its Research and Manufacturing obligations under this Agreement. Fate shall not grant any license or any right with respect to such Precursor iPSCs, Master iPSC Banks, or CD34 Compositions to any Third Party. Janssen shall not use any of its licensed rights in or to the Precursor iPSCs, Master iPSC Banks or CD34 Compositions under clause (y) of the Product License or clause (y) of the Manufacturing License other than as expressly permitted under ARTICLE 9. Given the nature of such Precursor iPSCs, Master iPSC Banks, and CD34 Compositions, and the competitive damage that may result to a Party upon unauthorized use of such Precursor iPSCs, Master iPSC Banks, and CD34 Compositions, the Parties agree that monetary damages may not be a sufficient remedy for any breach of this Section 5.1.4(b). In addition to all other remedies, each Party shall be entitled to seek specific performance and injunctive and other equitable relief as a remedy for any breach or threatened breach of this Section 5.1.4(b) by the other Party.

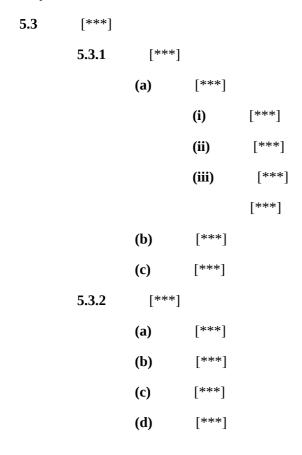
(c) [\*\*\*].

**5.1.5 Fate Affiliates**. If any of the Patents or Know-How licensed by Fate to Janssen pursuant to this Section 5.1 or Section 5.4 is Controlled by an Affiliate of Fate (but excluding any Patents and Know-How that are deemed not to be Controlled by Fate or its Affiliates pursuant to Section 17.14.1), Fate shall procure that such Affiliate grants the licenses to Janssen in accordance with this Section 5.1 or Section 5.4.

#### 5.2 License to Fate.

- **5.2.1 Research License.** Subject to the terms and conditions of this Agreement, during the Antigen Research Term for each Janssen Antigen, Janssen hereby grants to Fate a non-exclusive, royalty-free, non-transferable (except as permitted under Section 17.4) license in the Territory, with the right to grant sublicenses solely in accordance with Section 5.5.1, under Janssen Research Patents and Janssen Research Know-How solely as and to the extent necessary to enable Fate to perform Fate's obligations as set forth under the Research Plan for each Janssen Antigen (including through the engagement of subcontractors in accordance with Section 3.9). For the avoidance of doubt, if Janssen does not exercise its Commercial Option with respect to any Collaboration Candidates under a Research Program during the applicable Commercial Option Term in accordance with Section 4.3, the research license granted to Fate under this Section 5.2 shall expire with respect to all such Collaboration Candidates under such Research Program upon expiration of such last-to-expire Commercial Option Term.
- ARTICLE 9), upon and as of the Exercise Effective Date for a Licensed Collaboration Candidate and for the remainder of the Term for such Licensed Collaboration Candidate, Janssen hereby grants to Fate a co-exclusive (with Janssen), non-transferable (except as provided in Section 17.4) license (or sublicense, as applicable), with the right to grant sublicenses solely in accordance with Section 5.5 and Section 9.10, under the Janssen Product Patents and Janssen Product Know-How solely to: (x) Manufacture and have Manufactured such Licensed Collaboration Candidate and Licensed Products containing such Licensed Collaboration Candidate in the Field in the Territory and (y) use Master iPSC Banks and CD34 Compositions corresponding to such Licensed Collaboration Candidate for the Manufacture of such Licensed Collaboration Candidate and Licensed Products containing such Licensed Collaboration Candidate in the Field in the Field in the Territory.

- **5.2.3 Limitation of License; Retained Rights of Janssen.** For clarity, (a) the licenses granted to Fate under this Section 5.2 do not include the right for Fate to practice the Janssen Research Patents, Janssen Research Know-How, Janssen Product Patents or Janssen Product Know-How in a manner other than as expressly permitted under this Section 5.2 or Section 5.4 or ARTICLE 9; and (b) Janssen retains all rights to practice the Janssen Research Patents, Janssen Research Know-How, Janssen Product Patents or Janssen Product Know-How for any and all purposes, other than those expressly limited by license under Section 5.2, subject only to Section 5.1.4(b) and Section 5.10.
- **5.2.4 Janssen Affiliates**. If any of the Patents or Know-How licensed by Janssen to Fate pursuant to this Section 5.2 or Section 5.4 is Controlled by an Affiliate of Janssen, Janssen shall procure that such Affiliate grants the licenses to Fate in accordance with this Section 5.2 or Section 5.4.
- **5.2.5 Definition of Co-Exclusive**. For purposes of Section 5.1.2(a)(ii) and Section 5.2.2, "co-exclusive (with Fate)" or "co-exclusive (with Janssen)" means that the granting Party shall retain all of the same rights granted to the other Party under the intellectual property rights licensed thereunder. The granting Party covenants not to grant to any Third Party, without the prior written consent of the other Party, a license under such retained rights to conduct the activities licensed to the other Party.



- (e) [\*\*\*] [\*\*\*] (i) (ii) [\*\*\*] (iii) [\*\*\*] [\*\*\*] (iv) 5.3.3 [\*\*\*] (a) [\*\*\*] **(b)** [\*\*\*] (i) [\*\*\*] (ii) (iii) [\*\*\*] [\*\*\*] **(c)** [\*\*\*] 5.3.4 5.3.5 [\*\*\*] [\*\*\*] 5.3.6 5.3.7 [\*\*\*] (a) [\*\*\*] **(b)** [\*\*\*] **(c)** (d)
- 5.4 Collaboration Intellectual Property.

5.4.1 [\*\*\*]

(a) Subject to obligations of non-disclosure as provided under this Agreement (including under ARTICLE 12), [\*\*\*].

(b) Subject to obligations of non-disclosure as provided under this Agreement (including under ARTICLE 12), [\*\*\*].

## 5.4.2 Research Program Inventions Cross License.

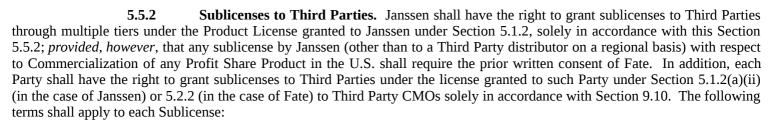
(a) Subject to the terms and conditions of this Agreement, each Party hereby grants to the other Party a non-exclusive, worldwide, perpetual, irrevocable, fully paid-up license, with the right to freely grant sublicenses through multiple tiers, under such first Party's rights and interests in any and all Research Program Inventions for all purposes (the "Research Program Inventions Cross License"); provided, however, that such Research Program Inventions Cross License does not include a grant of (i) any rights to either Party for any exploitation of any Collaboration Candidate, Licensed Collaboration Candidate or Licensed Product, or (ii) any rights to practice, other than Research Program Inventions, any Patents or Know-How owned or Controlled by such first Party or any of its Affiliates. For purposes of this Agreement, "Research Program Inventions" means [\*\*\*]. The foregoing Research Program Inventions Cross License shall not include the right for Janssen to practice any Fate Confidential Method or for Fate to practice any Janssen Confidential Method.

**(b)** The Parties acknowledge and agree that the Research Program Invention Cross License under this Section 5.4.2 does not include any Inventions conceived, developed or reduced to practice by or on behalf of either Party or any of its Affiliates either (i) prior to the Effective Date or (ii) after the Effective Date outside the scope of this Agreement (the "**Background IP**"). As such, to the extent a Party wishes to incorporate any of its proprietary technology under any Research Program or CMC Development Plan (A) that is Covered by any Patents within such Party's Background IP and (B) for which a license may be necessary for such other Party to practice Research Program Inventions, such [\*\*\*]. Janssen acknowledges that the Fate Research Patents set forth on **Exhibit 13.2.1** are Background IP of Fate.

5.4.3	Lice	ense for [***].
	(a)	[***]
	(b)	[***]
	(c)	[***]
	(d)	[***]

### 5.5 Sublicense.

**5.5.1 Sublicenses to Affiliates.** Each Party shall have the right to grant sublicenses of the licenses granted to such Party pursuant to Section 5.1, 5.2 or 5.4 to any of its Affiliates without the consent of the other Party; *provided, however*, that a Party shall not grant such a sublicense if such grant would cause adverse tax consequences to the other Party (or such Party's Affiliates), as reasonably demonstrated by such other Party within [\*\*\*] Business Days of being notified of a proposed sublicense. In the event a sublicense would so cause such adverse tax consequences, the Parties agree to cooperate reasonably to enable such sublicense in a manner reasonably satisfactory to the non-sublicensing Party, including, if appropriate, indemnification by the sublicensing Party.



- (a) Each Sublicense shall refer to this Agreement, shall be subordinate to and consistent with the terms and conditions of this Agreement, and shall not limit the ability of the sublicensing Party (individually or through the activities of its Sublicensee) to fully perform all of its obligations under this Agreement or the other Party's rights under this Agreement.
- **(b)** In such Sublicense, the Sublicensee shall agree to comply with all applicable terms and conditions of this Agreement.
- **(c)** Promptly after execution of the Sublicense agreement, the sublicensing Party shall provide a summary of such Sublicense to the other Party.
- **(d)** The sublicensing Party shall remain responsible for the performance of this Agreement and the performance of its Sublicensees hereunder.
- **(e)** Each Sublicense shall terminate immediately upon the termination of this Agreement (in whole or only with respect to the rights that are subject to such Sublicense).
- **(f)** The sublicensing Party shall obligate each of its Sublicensees to grant licenses to the sublicensing Party under any Patents and Know-How owned or controlled by such Sublicensee to enable the sublicensing Party to grant sublicenses to the other Party under such Patents and Know-How, to the extent that such Patents and Know-How would be licensed by the sublicensing Party to the other Party under the terms of this Agreement if such Patents and Know-How were solely owned by the sublicensing Party.

## 5.6 Functional Improvements; Next Generation Candidates.

**5.6.1 Notification of Functional Improvements.** If, [\*\*\*], Fate develops a Functional Improvement, Fate shall promptly disclose such Functional Improvement to Janssen (unless such Functional Improvement was developed jointly by the Parties in conduct of a Research Program). Janssen shall notify Fate if it desires to incorporate any such Functional Improvement of Fate, or any other Functional Improvement, into a Collaboration Candidate or Licensed Product, subject to the remainder of this Section 5.6, provided that, [\*\*\*], the Parties shall, prior to Fate's incorporation of such Functional Improvement into any Collaboration Candidate or Licensed Product, agree on the terms and conditions of such sublicense (e.g., the allocation of any payment obligations between Fate and Janssen such as royalty payment and royalty term, and the obligation for Janssen to comply with upstream obligations such as any [\*\*\*]).

- Janssen Right to Incorporate Functional Improvements. If Janssen notifies Fate that it desires to incorporate one or more Functional Improvement(s) into any one or more Collaboration Candidates from a Research Program [\*\*\*], subject to and in accordance with the remainder of this Section 5.6, provided that, [\*\*\*], the Parties shall, prior to Fate's incorporation of such Functional Improvement into any Collaboration Candidate or Licensed Product, agree on the terms and conditions of such sublicense (e.g., the allocation of any payment obligations between Fate and Janssen such as royalty payment and royalty term, and the obligation for Janssen to comply with upstream obligations such as any [\*\*\*]). The JRC shall update the applicable Research Plan(s) to include the activities necessary to incorporate such Functional Improvement into such Collaboration Candidate or Licensed Product, as applicable (such updated candidate, a "Next Generation Candidate"); provided, however, that in no event will a Next Generation Candidate be of a different CAR Cell Type than the original Collaboration Candidate or Licensed Product. Such amendment to the Research Plan shall in form and substance (including with respect to the activities to be conducted thereunder and the number of FTEs needed to conduct such activities) substantially follow the form and substance of the initial Research Plan for the Collaboration Candidate(s) or Licensed Product to be so updated. In the event the JRC does not reach consensus on the budget for the applicable Next Generation Candidate activities, then such budget shall equal [\*\*\*] of the budget set forth in the initial Research Plan for the Collaboration Candidate(s) or Licensed Product to be updated; provided, however, that no such Research Plan shall require Fate to conduct activities that, taken as a whole, would result in Fate incurring Research Costs in excess of the applicable Research Budget for such Research Plan. Upon such update, the [\*\*\*] pursuant to Section 3.4.2.
- **5.6.3 Research of Next Generation Candidates.** After the JRC updates the Research Plan to include activities for the Next Generation Candidate, the Parties shall conduct such activities in accordance with the Research Plan and the terms of ARTICLE 3. If the JRC selects any Next Generation Candidates to further develop in IND Enabling Studies in accordance with Section 3.7, then Janssen shall have the right to exercise the Commercial Option with respect to such Next Generation Candidates in accordance with Section 4.3. If Janssen exercises the Commercial Option with respect to any such Next Generation Candidate, then such Next Generation Candidate shall become a Licensed Collaboration Candidate (subject to Janssen paying to Fate the Option Exercise Payment in accordance with Section 10.2.4 in the event Janssen has not previously exercised the Commercial Option for any other Collaboration Candidate with respect to the applicable Janssen Antigen). Janssen shall not be obligated to discontinue the Development of the original Collaboration Candidate or Licensed Product that was the basis of such Next Generation Candidate.
- **5.6.4 Improvement Period**. With respect to any Licensed Product (i.e., after Janssen has exercised its Commercial Option), Janssen may implement Functional Improvements in accordance with and subject to Section 5.6.2 at any time during the Improvement Period for such Licensed Product. For clarity, if Janssen exercises the Commercial Option for a Next Generation Candidate, then the Improvement Period for the Licensed Product containing such Next Generation Candidate shall begin on the applicable Exercise Effective Date.
- **5.6.5 Research Costs for Next Generation Candidates.** Janssen shall be responsible for all Research Costs incurred to implement any Functional Improvement into Next Generation Candidates, pursuant to Section 10.2.

**5.6.6 Other Improvements.** If either Party develops or identifies a Functional Improvement that could be incorporated into a Collaboration Candidate or Licensed Product and such improvement is not subject to the terms of Section 5.6.1 through Section 5.6.5, either Party may propose the incorporation of such improvement to the JRC (or, if the JRC does not exist then, to the other Party) and the JRC (or the Parties) will determine, without any obligation, whether to incorporate such improvement and the terms for such incorporation, and if the JRC (or the Parties) does not agree to such incorporation by consensus, such improvement shall not be implemented.

## 5.7 Product Trademarks; Patent Marking.

- **5.7.1** Janssen shall be responsible for selection, prosecution, maintenance and enforcement of all Product Trademarks pertaining to the Licensed Products and for registering and maintaining all Product Domain Names and Websites. Janssen will own all right, title and interest in and to the Product Trademarks for the Licensed Products.
- **5.7.2** The packaging for each Licensed Product Commercialized by Janssen under this Agreement shall be marked with applicable patent notices relating to the Fate Product Patents in such a manner as may be permitted or required by Laws.
- **5.8 Third Party In-Licenses.** The licenses granted by Fate to Janssen under this ARTICLE 5 include sublicenses of rights licensed to Fate under the Existing Agreements. Janssen acknowledges and agrees that the licenses granted by Fate to Janssen under this ARTICLE 5 shall be non-exclusive with respect to any intellectual property that is non-exclusively licensed to Fate under an Existing Agreement. Prior to the Effective Date, [\*\*\*].

### 5.9 No Implied Licenses; Retained Rights; Government Rights.

- **5.9.1 No Implied Licenses, Retained Rights.** No license or other right is or shall be created or granted hereunder by implication, estoppel, or otherwise. All licenses and rights are or shall be granted only as expressly provided in this Agreement. All rights not expressly granted by either Party under this Agreement are reserved by such Party and may not be used by the other Party for any purpose.
- **5.9.2 Government Rights.** This Agreement is expressly subject to the reservation on behalf of the U.S. government under 35 U.S.C. § 200–212 and regulations promulgated thereunder. Each Party shall take all action necessary on its part, including the provision of additional information and supporting documentation to the other Party as reasonably requested by the other Party, to enable each Party to satisfy or to seek waivers with respect to its respective obligations under 35 U.S.C. § 200–212 and regulations promulgated thereunder. None of the Fate Research Patents, Fate Research Know-How, Fate Product Patents or Fate Product Know-How are or include any invention that was conceived or first actually reduced to practice in the performance of work under a funding agreement between Fate and the U.S. government.

### 5.10 Exclusivity and Other Restrictions.

### 5.10.1 During Exclusivity Period.

- (a) During the Exclusivity Period, [\*\*\*]. Notwithstanding the foregoing, either Party may acquire or maintain an ownership interest in a Third Party that owns or controls a Competing Product (for so long as such Third Party is not an Affiliate of such Party). For clarity, each Party will retain the right (and Fate will retain the right to use the Fate Platform Technology), including during the Exclusivity Period, to research, develop, manufacture and commercialize any product, including a cell product targeting any antigen (including a Janssen Antigen), so long as such product is not a Competing Product.
- **(b)** "Exclusivity Period" means, with respect to a Janssen Antigen, the period beginning on the Effective Date (or, with respect to Janssen Antigen 3 and Janssen Antigen 4, on the date that Janssen selects such antigen pursuant to Section 3.2.2) and, unless the Parties agree otherwise, ending:
  - (i) [\*\*\*]
  - (ii) [\*\*\*];

*provided*, *however*, that if the Research Program or this Agreement is terminated with respect to such Janssen Antigen before the date described in clause (i) or (ii), the Exclusivity Period will end on the effective date of such termination with respect to such Janssen Antigen. [\*\*\*].

- 5.10.2 Restricted Activities after Expiration of Commercial Option; Restriction on Use of Janssen Antigen Binding Domains.
- (a) If Janssen does not exercise the Commercial Option with respect to a particular Pre-IND Collaboration Candidate during the Commercial Option Term, then, following the expiration of the Commercial Option Term for such particular Pre-IND Collaboration Candidate, such Pre-IND Collaboration Candidate will be deemed a [\*\*\*].
- **(b)** During the Term with respect to a Janssen Antigen, neither Fate nor any of its Affiliates shall use, nor have any right to use, any Janssen Antigen Binding [\*\*\*], in each case with respect to such Janssen Antigen, except to the extent necessary to perform Fate's obligations under ARTICLE 3 and ARTICLE 9. For clarity, this Section 5.10.2(b) will not survive expiration of the Term with respect to a Janssen Antigen.
- **5.10.3 Change of Control.** If, as of the date of consummation of a Change of Control of Fate, the Acquirer of Fate in such Change of Control transaction is conducting on-going activities with respect to a Competing Product that are prohibited under Section 5.10.1, the restrictions in Section 5.10.1 shall not preclude the Acquirer from conducting such activities with respect to such Competing Product after the consummation of the Change of Control transaction, so long as during the applicable Exclusivity Period the Acquirer Segregates the program and activities related to the Competing Product from Fate's activities under this Agreement in accordance with Section 17.14.2.

- **5.10.4 Acquisition of Competing Products**. In the event that either Party or any of its Affiliates acquires rights to any Competing Product as the result of a merger, acquisition, combination or similar transaction with, of or by a Third Party, and as of the date of consummation of such transaction, there are on-going activities with respect to such Competing Product that are prohibited under Section 5.10.1, then the Party who acquired (or whose Affiliate acquired) such rights to such Competing Product ("**Acquiring Party**") shall notify the other Party of such transaction within [\*\*\*] Business Days after the consummation of such transaction and will promptly Segregate the program and activities related to the Competing Product from its activities under this Agreement in accordance with Section 17.14.2 and shall, within [\*\*\*] months after the date of consummation of such transaction, notify the other Party in writing whether it (or its Affiliate) will:
- (a) enter into a definitive agreement with a Third Party to divest such Competing Product within [\*\*\*] months after the consummation of such transaction; or
- **(b)** discontinue or terminate its activities with respect to such Competing Product no later than [\*\*\*] months after the closing of such transaction, until the expiration of the then-current Exclusivity Period with respect to the applicable Janssen Antigen.

Failure to provide timely notice will be deemed an election under clause (b). The Acquiring Party shall be permitted to continue Developing, Manufacturing or Commercializing such Competing Product during the applicable time period set forth in clause (a) or (b) above, and the applicable prohibition under Section 5.10.1 shall not apply during such applicable time period with respect to such Competing Product, *provided* that the Acquiring Party Segregates the activities with respect to such Competing Product from any activities under this Agreement.

**5.10.5 Effect of Transfer of Fate Intellectual Property**. Neither Fate nor any of its Affiliates shall sell or otherwise transfer the ownership of any Fate Research Know-How, Fate Research Patents, Fate Product Know-How or Fate Product Patents to any Third Party (including through a sale or ownership transfer by an Affiliate of Fate that Controls such intellectual property) without imposing on such Third Party the restrictions set forth in Section 5.10.1 solely with respect to its use of the Fate Research Know-How, Fate Research Patents, Fate Product Know-How or Fate Product Patents.

# ARTICLE 6 FATE OPT-IN OPTION

**6.1 Grant of Fate Opt-In Option**. For each Licensed Product, Janssen hereby grants to Fate the right to elect, at Fate's sole discretion, to co-fund Development in the Territory, and to co-Commercialize and share profits and losses in the U.S. with Janssen, with respect to such Licensed Product on the terms set forth in the Profit Share Product Exhibit (each, a "**Fate Opt-In Option**"), exercisable in accordance with the terms and conditions set forth in this ARTICLE 6.

- **6.2 Delivery of POC Data Packages**. Janssen shall notify Fate promptly [\*\*\*] for each Licensed Product. Within [\*\*\*] days thereafter, Fate shall notify Janssen of whether it desires to have Janssen prepare a data package with respect to such Licensed Product (the "**POC Data Package**" for such Licensed Product), which POC Data Package shall include:
- (a) all available safety and efficacy data (including the raw tables, figures and listings datasets) with respect to such Licensed Product through the [\*\*\*];
  - **(b)** a report of [\*\*\*];
- (c) Janssen's then-current internal clinical development plan and budget for such Licensed Product (which would include total Shared Development Costs by year by study only) to Develop such Licensed Product in the Territory for the [\*\*\*]-year period following the [\*\*\*]; and
- **(d)** Janssen's then-current internal marketing and commercialization plan and budget for such Licensed Product, which shall include, at a minimum, a [\*\*\*] for such Licensed Product.

If Fate requests the POC Data Package for such Licensed Product, then Janssen shall provide such POC Data Package to Fate within [\*\*\*] days after such request. If Janssen delivers a POC Data Package and Fate notifies Janssen within [\*\*\*] days following receipt that such POC Data Package is not complete and such notice specifies the information, data or results not included in such POC Data Package, Janssen shall provide the missing information, data or results as soon as possible and no later than [\*\*\*] days after Fate's notification. The date on which Fate is in receipt of a complete POC Data Package for a Licensed Product shall be deemed the "POC Data Package Delivery Date" with respect to such Licensed Product. Janssen shall promptly make available such other material information, data and results relating to such Licensed Product as Fate may reasonably request in order to make an informed decision regarding whether to exercise its Fate Opt-In Option with respect to such Licensed Product, including documentation supporting the then-current internal clinical development plan and budget and the then-current internal marketing and commercialization plan and budget, for such Licensed Product.

Notwithstanding the foregoing, if Fate requests the POC Data Package for a Licensed Product and Janssen has decided not to conduct any further Development of such Licensed Product, then Janssen shall deliver the POC Data Package, but the Fate Opt-In Option shall not apply to such Licensed Product unless and until Janssen decides to recommence Development of such Licensed Product (in which case Janssen shall provide Fate with prompt written notification thereof and the Fate Opt-In Option shall then apply).

**6.3 Exercise of Fate Opt-In Option.** Fate may exercise the Fate Opt-In Option for such Licensed Product by providing written notice of exercise to Janssen within [\*\*\*] days after the POC Data Package Delivery Date (the first Business Day after Fate's giving of such notice, the "**Opt-In Exercise Date**"). The Licensed Product as to which Fate has exercised the Fate Opt-In Option in accordance with this Section 6.3 shall be deemed to be a Profit Share Product as of the Opt-In Exercise Date and for the remainder of the applicable Profit Share Term.

**6.4 Consequences of Exercise of Fate Opt-In Option**. On and after the Opt-In Exercise Date for a Licensed Product, the terms and conditions set forth on **Exhibit 6.4** (the "**Profit Share Product Exhibit**") shall apply with respect to such Profit Share Product. All provisions of this Agreement shall continue to apply to the Profit Share Product, except to the extent expressly set forth in this Agreement or the Profit Share Product Exhibit.

# ARTICLE 7 DEVELOPMENT AND COMMERCIALIZATION

- **7.1 General.** From and after the Exercise Effective Date with respect to a particular Licensed Collaboration Candidate, Janssen (itself or through its Affiliates or its or their Sublicensees), at its sole cost and expense, shall have the sole right and authority to Develop and Commercialize, subject to Section 4.4, in the Territory such Licensed Collaboration Candidate and the Licensed Products containing such Licensed Collaboration Candidate, subject to the Fate Opt-In Option. Janssen shall conduct such activities in accordance with the terms and conditions of this Agreement.
- **7.2 Restriction on** [\*\*\*]. With respect to any Licensed Product containing a Licensed Collaboration Candidate that incorporates the Existing Functional Element described in Section 1.57(a), Janssen shall not [\*\*\*].
- **7.3 Standards of Conduct; Records.** Janssen shall conduct all Development of Licensed Products in good scientific manner and in compliance with all applicable Law, including GMP, GLP and GCP, as applicable. Janssen shall maintain, consistent with its then-current internal policies and practices, and cause its employees and Subcontractors to maintain, records and laboratory notebooks of its Development activities under this Agreement in sufficient detail and in a good scientific manner appropriate for regulatory and intellectual property protection purposes. Janssen shall conduct all Commercialization activities under this Agreement in compliance with all applicable Laws.
- **7.4 Development Reports.** In advance of each JSC meeting, unless otherwise agreed between the Parties, Janssen shall provide to the JSC a high-level summary report summarizing its Development activities with respect to each Licensed Product and the results thereof since the previous JSC meeting, and its anticipated Development activities with respect to each Licensed Product for the subsequent calendar quarter. At each JSC meeting, Janssen shall provide additional information as reasonably requested by Fate's JSC representatives with respect to the Development activities summarized in such report or otherwise conducted or anticipated to be conducted for Licensed Products.
- **7.5 Commercialization Reports.** On a semi-annual basis after Marketing Approval of any Licensed Product, Janssen shall provide to the JSC a high-level summary report of its Commercialization launch status, activities, and performance with respect to each Licensed Product since the previous JSC summary. At each JSC meeting, Janssen shall provide additional information as reasonably requested by Fate's JSC representatives with respect to the Commercialization activities summarized in such report or otherwise conducted or anticipated to be conducted for each Licensed Product.

- **7.6 Diligence.** If Janssen exercises the Commercial Option with respect to one or more Collaboration Candidates for a particular Janssen Antigen in accordance with Section 4.3, the following provisions of this Section 7.6 shall apply with respect to such Janssen Antigen:
  - (a) Janssen shall use [\*\*\*]Efforts to [\*\*\*];
  - **(b)** Following [\*\*\*] Janssen shall use [\*\*\*] Efforts to [\*\*\*]; and
- (c) For clarity, if Janssen [\*\*\*], Janssen is not obligated under this Section 7.6 to exercise [\*\*\*] Efforts to [\*\*\*].

If Fate exercises the Fate Opt-In Option with respect to a Licensed Product pursuant to Section 6.3, then, during the Profit Share Term for such Profit Share Product, the foregoing provisions of Section 7.6 shall not apply to such Profit Share Product, any Related Licensed Products or the applicable Janssen Antigen. Instead, Section 5.2 of the Profit Share Product Exhibit shall apply.

**7.7 Subcontracting.** Janssen may subcontract the performance of any Development and Commercialization activities for a Licensed Product under this Agreement to one or more Third Parties (each, a "**Subcontractor**"); *provided, however*, that: (a) any such Subcontractor (other than a CRO) to whom Janssen discloses Confidential Information of Fate shall enter into an appropriate written agreement obligating such Subcontractor to be bound by obligations of confidentiality and restrictions on use of such Confidential Information that are no less restrictive than the obligations in ARTICLE 12; (b) Janssen shall not disclose to such Subcontractor any Fate Confidential Methods without Fate's express prior written consent, which may be withheld in Fate's sole discretion on a case-by-case basis; (c) Janssen will obligate such Subcontractor (other than a CRO) to agree in writing to assign or license (with the right to grant sublicenses) to Janssen any inventions (including any Patents and Know-How covering such inventions) made by such Subcontractor in performing such activities, to the extent necessary for Janssen to (i) grant a license to Fate under such inventions as if such inventions were made by Janssen, and (ii) make the assignments to Fate contemplated in Section 11.1.2 with respect to such inventions (as if such inventions were made by Janssen); and (d) Janssen shall at all times be responsible for the performance of such Subcontractor and shall remain primarily responsible to Fate for the fulfillment of its obligations under this Agreement even after such activities are subcontracted to such Subcontractor.

# ARTICLE 8 REGULATORY

**8.1 General.** From and after the Exercise Effective Date with respect to a particular Licensed Collaboration Candidate or Licensed Products containing such Licensed Collaboration Candidate, subject to Sections 4.4.3 and 8.2, Janssen (itself or through its Affiliates or its or their Sublicensees), at its sole cost and expense, shall have the sole right to prepare and submit all Regulatory Filings (including BLAs, MAAs and Supplemental Applications), to obtain and maintain all Regulatory Approvals (including Marketing Approvals and Commercialization Approvals), and to conduct communications with Regulatory Authorities in the Territory. With respect to each Licensed Collaboration Candidate, [\*\*\*], (a) (i) Fate shall have the right to have one (1) representative attend all meetings (including by telephone), conferences and discussions between Janssen or its Affiliate and the FDA pertaining to such Licensed Product; and (ii) Janssen shall, to the extent feasible, provide Fate with reasonable advance notice of all such meetings and other contacts and advance copies of all related documents and other relevant information relating to such meetings or other contacts; and (b) Janssen shall provide Fate with each such Regulatory Filing [\*\*\*] sufficiently in advance for Fate's review and comment. Janssen shall [\*\*\*] any such comment from Fate [\*\*\*] (unless Janssen reasonably determines that such comment is not in compliance with applicable Law).

### 8.2 Transition of Existing Regulatory Filings and Regulatory Approvals.

**8.2.1** If Janssen exercises the Commercial Option with respect to a Licensed Collaboration Candidate in accordance with Section 4.3, Fate shall promptly provide Janssen with advance drafts of any documents or other correspondence pertaining to the IND application that Fate plans to submit to the applicable Regulatory Authority for the Licensed Product containing such Licensed Collaboration Candidate, and Fate shall promptly submit such IND application to the FDA, in accordance with and subject to Section 4.4.3. Fate shall provide Janssen with copies of all material submissions it makes to, and all material correspondence (including written summaries of material oral correspondence) it receives from, the applicable Regulatory Authority with respect to such IND application in accordance with this Section 8.2. Notices, copies of submissions and correspondence, and other materials to be given in advance as provided in this Section 8.2 shall be provided to Janssen in a timely manner as to allow Janssen a reasonable amount of time to review such notices, copies of submission and correspondence and materials before their submission to the applicable Regulatory Authority, and in any event at least [\*\*\*] Business Days in advance, unless circumstances necessitate a shorter time period. Correspondence and other documents received from a Regulatory Authority with respect to such IND application must be provided to Janssen as soon as practicable, and in any event within [\*\*\*] Business Days.

- **8.2.2** Prior to the transfer of the IND application for a particular Licensed Product as further described in Section 8.2.3 but after Janssen exercises the Commercial Option with respect to a Licensed Collaboration Candidate in accordance with Section 4.3, subject to applicable Law, (a) Janssen shall have the right to have one (1) representative attend all meetings (including by telephone), conferences and discussions between Fate or its Affiliate and the FDA pertaining to such Licensed Product; (b) Fate shall, to the extent feasible, provide Janssen with reasonable advance notice of all such meetings and other contacts and advance copies of all related documents and other relevant information relating to such meetings or other contacts; and (c) in advance of submission to the FDA, Fate shall provide Janssen, for Janssen's review and comment, any information or communications relating to the clinical protocol included in such IND or any other portion of the IND prepared by Janssen, and Fate shall reasonably consider any such comments from Janssen.
- **8.2.3** As soon as practicable after the date on which the IND submitted to the FDA by Fate for a particular Licensed Product pursuant to Section 4.4.3 becomes effective in the U.S. under 21 C.F.R. 312.40, Fate shall transfer to Janssen electronic copies (unless otherwise required by applicable Law) of all Regulatory Filings relating to such Licensed Product, including [\*\*\*].
  - **8.2.4** The Parties acknowledge that any [\*\*\*].
- Regulatory Filings, and shall promptly (and in any case within [\*\*\*] days) take all steps reasonably necessary to effectuate the assignment of all IND/CTAs included in such Regulatory Filings, including submitting to any applicable Regulatory Authority a letter or other necessary documentation (with copy to Janssen) notifying the Regulatory Authority of the assignment, for such Licensed Product. In the event that any such IND/CTA cannot be transferred within such [\*\*\*]-day period, Fate shall [\*\*\*] with respect to the maintenance or transfer of such IND/CTA. Fate shall have the right to retain ownership of any and all Regulatory Filings referenced by the IND prepared in accordance with Section 4.4.3 (but not including the IND itself, which shall be owned by Janssen) that are not specific to the applicable Licensed Product; *provided*, *however*,[\*\*\*]. In the event that any such IND/CTA includes any referenced Regulatory Filings, Fate will maintain compliance with all relevant U.S. Drug Master File (DMF) regulations or the equivalent as required in any country or region outside the U.S., and Fate will respond in a timely manner to all DMF Regulatory Authority audits/questions/findings. It is understood that DMF data is Fate Confidential Information. However, Fate will provide Janssen notice of DMF submissions and correspondence, and other materials as appropriate as soon as practicable, and in any event within [\*\*\*] days, unless circumstances necessitate a shorter time period to allow Janssen advance notice to address implications to Janssen's regulatory filings.
- **8.2.6** For clarity, any Fate Confidential Method disclosed to Janssen as a result of Fate's performance of its obligations under this ARTICLE 8 shall remain Fate Confidential Method, and such Fate Confidential Method shall remain subject to the terms and conditions of Section **Error! Reference source not found.**

### 8.3 Right of Reference.

- 8.3.1 Janssen shall have the right to cross-reference Fate's Regulatory Filings to the extent reasonably necessary to comply with a request from a Regulatory Authority in connection with the Development, Manufacture or Commercialization of Licensed Products by Janssen under this Agreement, including to any DMF or master files within the possession and control of Fate or its Affiliates, to the extent such DMF or master files specifically relate to the Licensed Products (the "Licensed Product DMFs"). [\*\*\*], subject to Sections 5.3.2(b) and 9.9.1. Fate hereby grants, and will cause its Affiliates to grant, to Janssen and its Affiliates and Sublicensee a "Right of Reference," as that term is defined in 21 C.F.R. § 314.3(b) in the United States, or an equivalent right of access/reference in any other country or region, to any such Regulatory Filings for use by Janssen to Develop, Manufacture and Commercialize Licensed Products pursuant to this Agreement. Fate shall provide a signed statement to this effect, if requested by Janssen, in accordance with 21 C.F.R. § 314.50(g)(3) or the equivalent as required in any country or region or otherwise provide appropriate notification of such right of Janssen to the applicable Regulatory Authority and shall cause its Affiliates to provide such signed statement. Fate will provide, and will cause its Affiliates to provide, cooperation to Janssen to effect the foregoing.
- **8.3.2** Fate shall have the right to cross-reference Janssen's Regulatory Filings for Licensed Products to the extent reasonably necessary to comply with a request from a Regulatory Authority in connection with the development or commercialization of products by Fate and its Affiliates (other than Collaboration Candidates and Licensed Products) [\*\*\*]. Janssen hereby grants, and will cause its Affiliates to grant, to Fate and its Affiliates a "Right of Reference," as that term is defined in 21 C.F.R. § 314.3(b) in the United States, or an equivalent right of access/reference in any other country or region, to any such Regulatory Filings for use by Fate and its Affiliates to develop and commercialize such products. Janssen shall provide a signed statement to this effect, if requested by Fate, in accordance with 21 C.F.R. § 314.50(g)(3) or the equivalent as required in any country or region or otherwise provide appropriate notification of such right of Fate to the applicable Regulatory Authority and shall cause its Affiliates to provide such signed statement. Janssen will provide, and will cause its Affiliates to provide, cooperation to Fate to effect the foregoing.
- **8.4 Regulatory Assistance.** As soon as practicable after the date on which the IND submitted to the FDA by Fate for a particular Licensed Product pursuant to Section 4.4.3 becomes effective in the U.S. under 21 C.F.R. 312.40, Fate shall reasonably cooperate with Janssen to provide regulatory assistance with respect to such Licensed Product, as reasonably requested by Janssen, to facilitate Regulatory Filings and communications with Regulatory Authorities in the Territory for such Licensed Product; *provided*, *however*, that the foregoing shall not be construed as requiring Fate to transfer or disclose to Janssen any Fate Confidential Methods except as expressly set forth under and subject to the terms and conditions of Section **Error! Reference source not found.**. Fate's reasonable cooperation as set forth above may be conducted by providing Janssen with reasonable access by teleconference or, during a period of [\*\*\*] months after the submission of such IND, in-person at Fate's facilities to those Fate personnel knowledgeable with respect to such regulatory matters, if any.

## 8.5 Pharmacovigilance Agreement.

- **8.5.1** Prior to the commencement of a Clinical Trial for a Licensed Product which incorporates an Existing Functional Element or Functional Improvement, should either Party reasonably believe there is a need to enter into a pharmacovigilance agreement setting forth the responsibilities and procedures for collecting, sharing and reporting to the applicable Regulatory Authorities safety information associated with such Licensed Product, so as to permit each Party to comply with applicable Laws and the requirements of Regulatory Authorities in relation to safety (a "**Pharmacovigilance Agreement**"), the Parties shall discuss in good faith and, if reasonably necessary, shall enter into a Pharmacovigilance Agreement.
- **8.5.2** If the Parties have not entered into a Pharmacovigilance Agreement pursuant to Section 8.5.1 with respect to a Licensed Product, then following the exercise of the Fate Opt-In Option for such Licensed Product, the Parties shall enter into a Pharmacovigilance Agreement with respect to such Licensed Product. Any Pharmacovigilance Agreement entered into pursuant to this Section 8.5 shall provide that Janssen shall be responsible for establishing and maintaining, and shall be the holder of, the global safety database for each Licensed Product.

# ARTICLE 9 MANUFACTURE AND SUPPLY

#### 9.1 CMC Development.

- **9.1.1 During the Antigen Research Term**. For each Research Program with respect to a Janssen Antigen, during the applicable Antigen Research Term and prior to Janssen's exercise of the Commercial Option for a particular Collaboration Candidate, as between Fate and Janssen:
- (a) Fate will be exclusively responsible for the conduct of, and shall use [\*\*\*] Efforts to conduct, for Collaboration Candidates, (i) the Cell Bank Process and Cell Bank Process Development; and (ii) the CD34 Composition Process and CD34 Composition Process Development, in each case, in accordance with the applicable Research Plan. Fate shall report its progress in conducting, and the results of such activities, at each meeting of the JMC. The JMC shall discuss and provide high-level oversight over such activities, but shall have no decision-making authority over such activities, other than [\*\*\*]. Within [\*\*\*] days of the Effective Date of the Agreement, Janssen shall provide the JMC with its customary safety and regulatory requirements, and its quality standards, for Manufacture of Collaboration Candidates, Licensed Collaboration Candidates and Licensed Products (the "Janssen Manufacturing Standards"); and shall provide any updates thereto promptly to Fate in writing, including through the JMC, during the Term.
- **(b)** [\*\*\*] conduct the Product Process and Product Process Development for Pre-IND Collaboration Candidates, including optimization of the existing, and development of improved, Product Processes for GMP Manufacturing, in accordance with the applicable Research Plan. [\*\*\*]. Fate will be responsible for conducting such activities in consultation with Janssen. [\*\*\*] shall report its progress in conducting, and the results of such activities, at each meeting of the JMC. The JMC shall oversee and make decisions with respect to such activities.

(c) All of the activities described in this Section 9.1.1 will be set forth in the Research Plan and the JRC and JMC will coordinate as appropriate with respect to such activities, including periodic process data review.

### 9.1.2 After Option Exercise.

- (a) Following Janssen's exercise of the Commercial Option for a Pre-IND Collaboration Candidate, Fate shall continue to be exclusively responsible for the Cell Bank Process Development, if any. Fate shall report its progress in conducting, and the results of such activities, at each meeting of the JMC. In addition, the JMC shall develop and approve a plan that sets forth the CMC Development activities to be undertaken with respect to the Licensed Collaboration Candidate and Licensed Products containing such Licensed Collaboration Candidate (the "CMC Development Plan").
- **(b)** The JMC shall allocate responsibility for activities in the CMC Development Plan between the Parties; *provided*, *however*, that Fate shall be exclusively responsible for [\*\*\*]. Each Party shall use [\*\*\*] Efforts to conduct the activities allocated to it under the CMC Development Plan.
- (c) Each CMC Development Plan shall include a rolling, [\*\*\*] year budget for CMC Development Costs to be incurred by each Party and its Affiliates in conducting the activities described in the CMC Development Plan that are scheduled to be commenced or conducted during the [\*\*\*] (with respect to such Calendar Years, the "CMC Development Budget"). The CMC Development Budget shall be broken down by Calendar Quarter and, for each Calendar Quarter, shall be broken down by CMC Development FTE Costs and Out-of-Pocket Expenses. The [\*\*\*] of the then-current CMC Development Budget [\*\*\*], and the [\*\*\*] shall serve as [\*\*\*].
- (d) The JMC shall review the applicable CMC Development Plan annually and prepare any recommended updates. No later than [\*\*\*] of the then-current Calendar Year, the JMC shall prepare an updated CMC Development Budget covering the [\*\*\*]. After each Party performs its internal budgeting process, the JMC shall use reasonable efforts to approve such updates no later than [\*\*\*] of each Calendar Year.
- **(e)** Either Party may propose amendments to the CMC Development Plan from time to time. The JMC shall discuss whether to approve such proposal at its next meeting. Such updates and amendments shall be effective upon JMC approval.
- **(f)** Following Janssen's exercise of the Commercial Option for a Pre-IND Collaboration Candidate, periodic process data review will occur at the JMC throughout the development of Licensed Products containing such Licensed Collaboration Candidate.

## 9.2 Fate Manufacturing Facilities; Facility Manufacturing Schedules.

- 9.2.1 As of the Effective Date, Fate has established a manufacturing facility in San Diego, California for the Manufacturing of CAR-NK Cells and CAR-T Cells (the "Existing Fate Facility"). The Existing Fate Facility may be used for certain Research Plan activities; and, in the event Fate is then-currently using the Existing Fate Facility to manufacture CAR-NK Cells or CAR-T Cells for use in a Phase II Trial conducted by Fate or any of its other licensees, such Existing Facility may be used to Manufacture Early Stage Clinical Supplies of Licensed Products, subject to completion of an audit of such facility pursuant to Section 9.3.2. In addition, Fate is planning to establish a separate manufacturing facility for the Manufacturing of CAR-NK Cells and CAR-T Cells (the "Planned Fate Facility"). Fate may also engage a Third Party manufacturer for the Manufacturing of CAR-NK Cells and CAR-T Cells on behalf of Fate at such Third Party's manufacturing facility (the "Back-Up Fate Facility") in accordance with Section 9.10.
- **9.2.2** At each meeting of the JMC, Fate shall provide an update on the status of its manufacturing facilities, including the operation of its Existing Fate Facility, and its progress toward establishing, validating and qualifying the Planned Fate Facility and, if applicable, the Back-Up Fate Facility. If Janssen identifies an issue with any of the facilities that could affect its status as a Compliant Clinical Manufacturing Facility or Compliant Commercial Manufacturing Facility, Janssen will promptly notify Fate. The JMC will then meet and develop a plan to correct such issues. For clarity, the JMC shall have no decision-making authority over Fate's manufacturing facilities.
- **9.2.3** [\*\*\*] for all costs of establishing, maintaining and operating the Existing Fate Facility, the Planned Fate Facility and, if applicable, the Back-Up Fate Facility, except to the extent such costs are expressly included in Research Costs, CMC Development Costs, or Cost of Goods for Licensed Product supplied to Janssen under this ARTICLE 9.
- **9.2.4** The JMC will review and align on the production schedule for all Licensed Products at all facilities on a rolling [\*\*\*] month basis.

# 9.3 Manufacture and Supply of Early Stage Clinical Supplies.

- **9.3.1** Within [\*\*\*] days following Janssen's exercise of the Commercial Option for a Pre-IND Collaboration Candidate, Janssen shall provide the JMC with a forecast of its requirements of clinical supplies of Licensed Products containing the Licensed Collaboration Candidate for use in non-Registration Studies (the "Early Stage Clinical Supplies").
- 9.3.2 Fate shall be solely responsible for Manufacturing all of Janssen's requirements of Early Stage Clinical Supplies of the Licensed Product. Such Manufacture by Fate may be conducted at either the Existing Fate Facility (subject to the requirements set forth in Section 9.2.1), the Planned Fate Facility, or the Back-Up Fate Facility (subject to Section 9.10), as selected by Fate; *provided*, *however*, that [\*\*\*], under Section 9.1.1(a) (a "Compliant Clinical Manufacturing Facility"). As soon as reasonably practicable following the Effective Date of this Agreement, if Fate selects the Existing Fate Facility to Manufacture Early Stage Clinical Supplies, Janssen shall conduct an initial audit of the Existing Fate Facility in accordance with Section 9.8. If Fate selects the Planned Fate Facility or the Back-Up Fate Facility to Manufacture Early Stage Clinical Supplies, Janssen shall also conduct an initial audit of such facility in accordance with Section 9.8 as soon as practicable after Fate establishes such facility. The results of such internal audit by Janssen will be shared with the JMC with the intent of assisting Fate in its efforts to comply with GMP (including FDA, EMA and Japanese GMP), all regulatory requirements, and the then-current Janssen Manufacturing Standards.

- 9.3.3 Within [\*\*\*] days following Janssen's exercise of the Commercial Option for a Pre-IND Collaboration Candidate, the Parties shall enter into a supply agreement setting forth the terms and conditions applicable to the Manufacture and supply of the Early Stage Clinical Supplies of the Licensed Products containing the Licensed Collaboration Candidate (the "Early Stage Clinical Supply Agreement") and a related quality agreement; provided, however, [\*\*\*]. The Early Stage Clinical Supply Agreement shall be consistent with the terms of this Agreement, and shall contain reasonable and customary terms for agreements of its type and for this type of product (including forecasting and ordering requirements, delivery, process development, technology transfer, termination, procedures for non-conformance with specifications and non-compliance with Laws, audit and inspection (including of books of accounts and records by Janssen for the determination of the Cost of Goods) and indemnification), as well as the following terms:
- (a) Fate shall Manufacture and supply to Janssen, and Janssen shall obtain from Fate, all of Janssen's requirements of Early Stage Clinical Supplies of such Licensed Products;
- **(b)** Fate shall Manufacture all Early Stage Clinical Supplies of Licensed Products, and all CD34 Composition and drug substance used to Manufacture such Licensed Products, in a Compliant Clinical Manufacturing Facility, and Janssen shall have the right to audit such facilities to the extent provided in Section 9.8;
- (c) the JMC shall oversee the operational aspects of the Manufacture and supply of Early Stage Clinical Supplies;
  - (d) supply shortage and failure to supply provisions, including [\*\*\*]; and
- **(e)** Early Stage Clinical Supplies of Licensed Product shall be supplied by Fate to Janssen at a supply price equal to [\*\*\*].

Until the Early Stage Clinical Supply Agreement is executed, the terms set forth in clauses (a) through (e) of this Section shall apply.

# 9.4 Manufacture and Supply of Pivotal Clinical Supplies and Initial Commercial Supplies.

- **9.4.1 Commercial Supply Criteria**. Promptly following the date on which the first IND of a Licensed Product becomes effective in the U.S. under 21 C.F.R. 312.40, the JMC will determine whether the Planned Fate Facility or the Back-Up Fate Facility complies with the Commercial Supply Criteria as follows:
- (a) Janssen shall provide the JMC with a forecast of its requirements of clinical supplies of the Licensed Product for use in Registration Studies (the "**Pivotal Clinical Supplies**"), and for commercial supplies for launch and for each of the [\*\*\*] years following launch, of such Licensed Product (the "**Initial Commercial Supplies**").

<b>(b</b> )	) Following re	eceipt of Janssen's f	forecast, Fate shal	l notify Janssen v	whether it wi	ill use the
Planned Fate Facility or the Bac	k-Up Fate Facility (	(subject to Section 9	9.10) for Manufac	ture of the Pivota	al Clinical Su	applies or
Initial Commercial Supplies. A	fter Fate so notifies	s Janssen, subject to	Section 9.4.1(f)	, Janssen shall co	onduct an au	dit of the
facility selected by Fate (i.e., th	e Planned Fate Faci	ility or the Back-Up	Fate Facility) in	accordance with	Section 9.8	and shall
submit its audit findings to the	JMC. The JMC sha	all review the audit	findings and deter	rmine whether th	e audited fac	ility is in
compliance with the Commercia	l Supply Criteria.					

(c) The "Commercial Supply Criteria" for determination of compliance will consist of: [\*\*\*]. The JMC may update the Commercial Supply Criteria from time to time.

**(d)** [\*\*\*] (a "Compliant Commercial Manufacturing Facility"), then Fate (at the Planned Fate Facility or the Back-Up Fate Facility, as applicable) shall have the obligation to Manufacture and supply to Janssen, and Janssen shall have the obligation to obtain from Fate, all of Janssen's requirements of Pivotal Clinical Supplies and Initial Commercial Supplies at such Compliant Commercial Manufacturing Facility and Section 9.4.2 shall apply.

(e) [\*\*\*].

**(f)** If Fate notifies Janssen that it will use the Planned Fate Facility to Manufacture Pivotal Clinical Supplies and Initial Commercial Supplies in accordance with Section 9.4.1(b) but, on the date on which the first IND of such Licensed Product becomes effective in the U.S. under 21 C.F.R. 312.40, [\*\*\*], then the following terms shall apply:

(i) Fate will provide Janssen with its plan for completing the establishment of the Planned Fate Facility, which plan shall include key milestone events and reasonable deadlines for achievement of such milestone events. Janssen will reasonably determine, in consultation with Fate, [\*\*\*]. If Janssen identifies any issues with the plan, the Parties shall meet, discuss and make appropriate modifications to such plan.

(ii) [\*\*\*]

(iii) [\*\*\*]

(iv) [\*\*\*].

**(g)** If, pursuant to Section 9.4.1(e), 9.4.1(f) or 9.4.2(b), Janssen Manufactures any Pivotal Clinical Supplies or Initial Commercial Supplies:

(i) the Parties shall enter into a supply agreement for the supply by Fate to Janssen of sufficient quantities of CD34 Composition for the Manufacture of Pivotal Clinical Supplies or Initial Commercial Supplies, under which Fate shall supply such CD34 Composition to Janssen, and Janssen shall obtain its requirements of such CD34 Composition from Fate, at a supply price equal to [\*\*\*] for Pivotal Clinical Supplies and at a supply price equal to [\*\*\*], for Initial Commercial Supplies; and

- (ii) such supply agreement shall contain reasonable and customary terms for, pursuant to which Fate shall conduct, [\*\*\*], technology transfer of the Product Process pursuant to Section 9.9 to the Janssen facility [\*\*\*] for Manufacture of Pivotal Clinical Supplies or Initial Commercial Supplies using such CD34 Composition.
- **9.4.2 Fate Manufacture of Pivotal Clinical and Commercial Supplies**. [\*\*\*], then the following provisions shall apply.
- (a) The JMC shall develop and approve a plan for Fate to qualify and validate the Compliant Commercial Manufacturing Facility for the Manufacture of the Pivotal Clinical Supplies and Initial Commercial Supplies of the Licensed Product, which plan shall include key milestone events and deadlines for achievement of such milestone events. Fate shall report on its progress under such plan at each meeting of the JMC in accordance with Section 9.2.
- **(b)** [\*\*\*], then Janssen shall have the right to Manufacture its requirements of Pivotal Clinical Supplies and Initial Commercial Supplies and the terms of Section 9.4.1(g) shall apply to such Manufacture.
- be solely responsible for Manufacturing and supply to Janssen, and Janssen shall obtain from Fate, all of Janssen's requirements of Pivotal Clinical Supplies and the Initial Commercial Supplies of the Licensed Product at the Compliant Commercial Manufacturing Facility. Within [\*\*\*] days following the JMC's determination, the Parties shall enter into a supply agreement setting forth the terms and conditions applicable to the Manufacture and supply of the Pivotal Clinical Supplies and Initial Commercial Supplies of the Licensed Product (the "Pivotal Clinical and Commercial Supply Agreement") and a related quality agreement; *provided*, *however*, [\*\*\*]. The Pivotal Clinical and Commercial Supply Agreement shall be consistent with the terms of this Agreement, and shall contain reasonable and customary terms for agreements of its type and for this type of product (including forecasting and ordering requirements, delivery, process development, technology transfer, termination, procedures for non-conformance with specifications and non-compliance with Laws, audit and inspection (including of books of accounts and records by Janssen for the determination of the Cost of Goods) and indemnification), as well as the following terms:
- (i) Fate shall Manufacture and supply to Janssen, and Janssen shall purchase from Fate, all units of Licensed Product that are forecasted and ordered by Janssen in accordance with the forecasting and ordering requirements set forth in the Pivotal Clinical and Commercial Supply Agreement;
- **(ii)** Fate shall Manufacture and supply to Janssen, and Janssen shall purchase from Fate, all Pivotal Clinical Supplies and Initial Commercial Supplies of Licensed Product, and all CD34 Composition and drug substance used to Manufacture such Licensed Product, in the Compliant Commercial Manufacturing Facility, and Janssen shall have the right to audit such facilities to the extent provided in Section 9.8;

- **(iii)** Fate shall use [\*\*\*] Efforts to ensure uninterrupted supply of any Licensed Product ordered by Janssen in accordance with the applicable forecasting and ordering requirements;
- **(iv)** the JMC shall oversee the operational aspects of the Manufacture and supply of Licensed Product, and all CD34 Composition and drug substance used to Manufacture such Licensed Product, including forecasting, ordering and planning to ensure business continuity with respect to the Manufacture and supply of Licensed Product;
  - **(v)** supply shortage and failure to supply provisions, [\*\*\*];
- **(vi)** Pivotal Clinical Supplies of Licensed Product shall be supplied by Fate to Janssen at a supply price equal to [\*\*\*]; and
- **(vii)** Initial Commercial Supplies of Licensed Product shall be supplied by Fate to Janssen at a supply price equal to [\*\*\*].

Until the Pivotal Clinical and Commercial Supply Agreement is executed, the terms set forth in clauses (i) through (vii) of this Section shall apply.

## 9.5 Manufacture and Supply of Other Commercial Supplies.

**9.5.1 Responsibility for Manufacture of Other Commercial Supplies**. Janssen shall have the right to Manufacture all of its requirements of commercial supplies of Licensed Products beyond the Initial Commercial Supplies at a Janssen facility or the facility of an Approved CMO.

#### 9.5.2 Transition of Manufacture to Janssen.

(a) If Fate is Manufacturing the Pivotal Clinical Supplies and Initial Commercial Supplies of a Licensed Product under Section 9.4.2, then promptly following BLA submission for such Licensed Product, the JMC shall meet to discuss [\*\*\*]. After the JMC discusses the allocation of responsibility for future commercial supplies of a Licensed Product, the JMC shall develop and approve a plan to transition the Manufacture of commercial supplies of such Licensed Product to Janssen. If the JMC does not approve such transition plan within [\*\*\*] days following BLA submission for such Licensed Product, then Janssen shall have final decision-making authority with respect to such transition plan. Such transition plan shall include activities necessary to complete a technology transfer of the Product Process pursuant to Section 9.9 to the facility(ies) of Janssen or an Approved CMO that will be used by Janssen to Manufacture such commercial supplies and activities necessary to validate and qualify such facility(ies). Each Party shall conduct the activities set forth in the transition plan. Unless and until Janssen's facilities are qualified, validated and approved by the applicable Regulatory Authority for the Manufacture of such supplies, Fate will continue to Manufacture commercial supplies at a Compliant Commercial Manufacturing Facility on the same terms and conditions that apply to the Initial Commercial Supplies.

<b>(b)</b>	Promptly following BLA submission for such Licensed Product, the Parties shall enter
into a supply agreement for the supply	by Fate to Janssen of sufficient quantities of CD34 Composition for Manufacture of sucl
commercial supplies of the Licensed Pr	oduct, under which Fate shall supply such CD34 Composition to Janssen at a supply price
equal to [***].	

(c) If Janssen has the right to Manufacture its requirements of Pivotal Clinical Supplies and Initial Commercial Supplies under Section 9.4.1(e), 9.4.1(f) or 9.4.2(b), then Fate shall have no right to Manufacture any of Janssen's requirements of future commercial supplies beyond the Initial Commercial Supplies, and Janssen shall Manufacture its requirements of future commercial supplies beyond the Initial Commercial Supplies at a Janssen facility or the facility of an Approved CMO. The terms of Section 9.4.1(g) shall apply to such supplies.

#### 9.6 Cell Banks.

- **9.6.1** Fate shall be responsible for generating the Master iPSC Bank for each Licensed Product. The JMC shall oversee the progress of the generation of the Master iPSC Bank and determine whether to generate working cell banks.
- **9.6.2** Upon Janssen's exercise of the Commercial Option for a Pre-IND Collaboration Candidate, [\*\*\*]. Unless the JMC determines otherwise, during the Term, the Master iPSC Bank shall be stored in at least two locations selected by the JMC, one of which will be a Fate manufacturing facility and one of which will be a location controlled by Janssen.
- **9.6.3** Each Party shall hold the Master iPSC Bank at a facility approved by the JMC. Fate shall use the Master iPSC Bank, and the Parties shall use CD34 Compositions, only to Manufacture Licensed Products as permitted under this Agreement. Neither Party shall permit any Third Party to access such Master iPSC Bank, except a Third Party manufacturer is permitted to receive vials from such Master iPSC Bank solely for the Manufacture of Licensed Products. With respect to any portion of the Master iPSC Bank stored by a Party, each Party acknowledges and agrees that:
- (a) the Master iPSC Bank shall be, and shall at all times during the Term remain, subject to Janssen's exclusive rights under Section 9.6.2;
- **(b)** each Party will use a control system to ensure the Master iPSC Bank is properly secured and has limited authorized access;
- (c) each Party will maintain the Master iPSC Bank under validated storage conditions designed to maintain viability, prevent contamination and otherwise maintain GMP compliance, and such storage conditions will be actively monitored and documented;
- (d) each Party will provide documentation upon request regarding the use of the vials from the Master iPSC Bank and monitored storage conditions, the foregoing shall not be construed to expand a Party's right to access or use of such Master iPSC Bank; and
- **(e)** each Party shall conspicuously mark the Master iPSC Bank as subject to the terms of this Section 9.6.3.

**9.6.4** [\*\*\*]; *provided*, *however*, that the Parties agree that Fate shall be the Party responsible for the regeneration of the Master iPSC Bank unless Fate is unable to carry out such responsibility. Except as set forth above, Fate shall have the exclusive right to conduct the Cell Bank Process and Cell Bank Process Development under this Agreement.

## 9.7 Compliance; Safety Issues.

- **9.7.1** Each Party shall conduct all CMC Development, Manufacturing and supply activities, including the manufacture, handling, storage and shipment of all applicable Collaboration Candidates and Licensed Products in compliance with all Laws (including all current governmental regulatory requirements concerning GMP and GMP requirements concerning documentation, reports and record keeping and relating to the protection of the environment and occupational health and safety), all Regulatory Filings, and its applicable internal specifications and quality control procedures. Fate shall conduct all Cell Bank Process Development in compliance with all Laws (including all current governmental regulatory requirements concerning GMP and GMP requirements concerning documentation, reports and record keeping and relating to the protection of the environment and occupational health and safety), all Regulatory Filings, and its applicable internal specifications and quality control procedures.
- **9.7.2** If Fate is Manufacturing any supplies of Licensed Products pursuant to this ARTICLE 9, and Janssen reasonably determines that there is a safety or quality issue with respect to any such supplies or the facility in which such supplies are Manufactured, [\*\*\*].
- **9.8** Audits. Each Party shall have the right to audit any facility where (a) the Master iPSC Bank or the CD34 Composition, or any working cell bank thereof, of a Licensed Collaboration Candidate is stored by the other Party or (b) CD34 Composition, drug substance or Licensed Products are Manufactured by the other Party (or any of its Affiliates or permitted CMOs) to ensure compliance with this ARTICLE 9. Any such audit shall be arranged on mutually convenient dates, shall involve no more than two (2) auditors, take no longer than [\*\*\*] Business Days and occur no more than once in any Calendar Year, except in circumstances in which an audit reveals issues requiring follow up visits. Any such audit visit will be subject to the Parties establishing appropriate confidentiality protections regarding the audited Party's manufacturing technology and any other products which may be made at the applicable facility. In the event of any inconsistency between this Section 9.8 and the audit provisions contained in any quality agreement entered into pursuant to this ARTICLE 9, the terms of such quality agreement shall prevail and govern.

# 9.9 Manufacturing Technology Transfer.

**9.9.1** [\*\*\*] Any Fate Confidential Methods disclosed to Janssen under this Section shall continue to be Fate Confidential Methods and shall continue to be subject to Section 5.3.

**9.9.2** In the event Janssen is or becomes responsible for the conduct of any Cell Bank Process, CD34 Composition Manufacturing, or Product Manufacturing for a Licensed Product in accordance with this ARTICLE 9, Fate shall reasonably cooperate with Janssen to provide technical assistance, and to transfer to Janssen, any applicable Fate Product Know-How, including any Fate Confidential Methods, licensed to Janssen under Section 5.1.2(a)(ii), used by Fate to conduct the applicable activity, at Janssen's cost and expense. The Parties acknowledge that any such transfer by Fate to Janssen will contain Fate Confidential Methods and therefore shall be subject to Section 5.3. Any Fate Confidential Methods transferred to Janssen under this Section shall continue to be Fate Confidential Methods and continue to be subject to Section 5.3.

## 9.10 Third Party Subcontractors.

- **9.10.1** Each Party (or its Affiliate) may subcontract the performance of any of its Manufacturing activities under this ARTICLE 9 to a Third Party (a "CMO") subject to the prior written consent of the other Party, which shall not be unreasonably withheld (such a CMO, an "Approved CMO"). In addition, if any activities to be conducted by a CMO reasonably requires the disclosure of any Fate Confidential Methods, the Parties will reasonably cooperate to identify a mutually acceptable CMO before engaging such CMO.
- **9.10.2** If Janssen desires to use a CMO to perform any of its Manufacturing responsibilities and Fate has previously engaged a CMO under this Section 9.10, then Janssen will engage Fate's CMO for such Manufacturing unless the Parties agree otherwise.

9.10.3 [\*\*\*]

**9.10.4** Each CMO must satisfy and comply with at all times GMP (including FDA, EMA and Japanese GMP), all regulatory requirements, and the then-current Janssen Manufacturing Standards; and must satisfy and comply with at all times any additional subcontractor criteria established by the JMC, which shall include the following requirements: (a) any such CMO to whom a Party discloses Confidential Information of the other Party shall enter into an appropriate written agreement obligating such CMO to be bound by obligations of confidentiality and restrictions on use of such Confidential Information that are no less restrictive than the obligations in ARTICLE 12; (b) [\*\*\*]; (c) the subcontracting Party shall at all times be responsible for the performance of such CMO and shall remain primarily responsible to the non-subcontracting Party for the fulfillment of its obligations under this Agreement even after such activities are subcontracted to such CMO.

# ARTICLE 10 FINANCIAL TERMS

**10.1 Upfront Payment**. In partial consideration for the rights granted to Janssen under this Agreement, Janssen shall pay to Fate a one-time-only, non-refundable, non-creditable upfront payment of Fifty Million Dollars (\$50,000,000) within ten (10) Business Days after the Effective Date.

# 10.2 Payments during Research Term.

- **10.2.1 Fate Research Costs.** As consideration for Fate's conduct of the Research Plan activities, Janssen shall reimburse Fate for all Research Costs incurred by Fate and its Affiliates on the terms set forth in this Section. Within [\*\*\*] days after the end of each [\*\*\*], Fate shall submit to Janssen a report, in a format established by the Parties, of all Research Costs incurred by Fate and its Affiliates to conduct activities under each Research Plan during such Calendar Quarter (the "**Research Cost Report**"). Within [\*\*\*] days following the receipt of the Research Cost Report, Janssen shall have the right to request reasonable additional information, including documentation of Out-of-Pocket Expenses, related to Fate's and its Affiliates' Research Costs during such Calendar Quarter. Janssen shall pay Fate an amount equal to the Research Costs reported in the Research Cost Report within [\*\*\*] days after the end of the applicable [\*\*\*]; provided, however, that Research Costs incurred in performing activities under a Research Plan that exceed the total amount set forth in the applicable Research Budget in the applicable Calendar Year-to-date period shall be included in the calculation of Research Costs to be reimbursed by Janssen only to the extent such excess Research Costs do not exceed [\*\*\*] of the total amount set forth in such Research Budget in the applicable Calendar Year-to-date period in accordance with such Research Budget for such Calendar Year.
- **10.2.2 Janssen Research Costs**. Janssen shall bear, and shall be fully and solely responsible for, all costs incurred by Janssen and its Affiliates under each Research Plan.
- **10.2.3 Research Milestone Payments.** On a Janssen Antigen-by-Janssen Antigen basis, Janssen shall pay to Fate a milestone payment of [\*\*\*] Dollars (\$[\*\*\*]) within [\*\*\*] days after the Selection Date of the first Collaboration Candidate with respect to a particular Janssen Antigen that the JRC determines (or Janssen determines) to further develop in IND Enabling Studies pursuant to Section 3.7. The milestone payment set forth in this Section 10.2.3 shall be non-refundable and non-creditable and shall be payable no more than once for each Janssen Antigen, regardless of the number of Collaboration Candidates with respect to such Janssen Antigen that the JRC determines (or Janssen determines) to further develop in IND Enabling Studies. For clarity, if the JRC or Janssen does not determine to further develop in IND Enabling Studies any DC Collaboration Candidates with respect to a particular Janssen Antigen, all such DC Collaboration Candidates with respect to such Janssen Antigen shall become Discontinued Collaboration Candidates, this Agreement shall be deemed terminated with respect to such Janssen Antigen and such Janssen Antigen shall cease to be a Janssen Antigen, and no milestone payment under this Section 10.2.3 shall be payable with respect to such Janssen Antigen.

- **10.2.4 Option Exercise Payments.** On a Janssen Antigen-by-Janssen Antigen basis, Janssen shall pay to Fate an option exercise fee of [\*\*\*] Dollars (\$[\*\*\*]) (the "**Option Exercise Payment**") the first time Janssen exercises the Commercial Option for a Collaboration Candidate with respect to a particular Janssen Antigen in accordance with Section 4.3. For clarity, if Janssen has previously exercised the Commercial Option for a different Collaboration Candidate with respect to the same Janssen Antigen as such Collaboration Candidate, then no payment shall be due for the exercise of the Commercial Option for any subsequent Collaboration Candidates with respect to the same Janssen Antigen. The Option Exercise Payment shall be paid within [\*\*\*] days after the applicable Exercise Effective Date.
- **10.3 Effect of Commercial Option Exercise.** The provisions of Section 10.4 through Section 10.8 shall apply to Licensed Products that contain Collaboration Candidates for which Janssen exercised the Commercial Option in accordance with Section 4.3.

### 10.4 Clinical Development and Regulatory Milestones.

10.4.1 Clinical Development Milestone Events and Payments. Subject to Sections 10.4.4 and Section 10.8, in consideration of Fate's performance in achieving the following milestone events, Janssen shall pay to Fate the milestone payments set forth in the table below not later than [\*\*\*] days after Fate delivers an invoice to Janssen upon the first occurrence of the corresponding milestone event set forth below with respect to each Janssen Antigen (each, a "Clinical Development Milestone Event"). For clarity, with respect to each Janssen Antigen, the milestone payments set forth in this Section 10.4.1 shall be payable no more than once for each Janssen Antigen. Janssen shall provide notice to Fate within [\*\*\*] days after the occurrence of any of the Clinical Development Milestone Events:

Clinical Development Milestone Event		Milestone Payment						
	Janssen Antigen 1	Janssen Antigen 2	Janssen Antigen 3	Janssen Antigen 4				
Clinical Development Milestones								
1. [***]	\$[***]	\$[***]	\$[***]	\$[***]				
2. [***]	\$[***]	\$[***]	\$[***]	\$[***]				
3. [***]	\$[***]	\$[***]	\$[***]	\$[***]				

**10.4.2 Regulatory Milestones and Payments.** Subject to Section 10.4.4 and Section 10.8, in consideration of Fate's performance in achieving the following milestone events, Janssen shall pay to Fate the milestone payments set forth in the table below not later than [\*\*\*] days after Fate delivers an invoice to Janssen upon the first occurrence of the corresponding milestone event set forth below with respect to a Licensed Product (each, a "**Regulatory Milestone Event**"). For clarity, the milestone payments set forth in this Section 10.4.2 shall be payable for each Licensed Product. Janssen shall provide notice to Fate within [\*\*\*] days after the occurrence of any of the Regulatory Milestone Events:

Regulatory Milestone Event		Milestone 1	Payment	
	Janssen Antigen 1	Janssen Antigen 2	Janssen Antigen 3	Janssen Antigen 4
1. [***]	\$[***]	\$[***]	\$[***]	\$[***]
2. [***]	\$[***]	\$[***]	\$[***]	\$[***]
3. [***]	\$[***]	\$[***]	\$[***]	\$[***]
4. [***]	\$[***]	\$[***]	\$[***]	\$[***]
5. [***]	\$[***]	\$[***]	\$[***]	\$[***]
6. [***]	\$[***]	\$[***]	\$[***]	\$[***]
7. [***]	\$[***]	\$[***]	\$[***]	\$[***]
8. [***]	\$[***]	\$[***]	\$[***]	\$[***]
9. [***]	\$[***]	\$[***]	\$[***]	\$[***]
10. [***]	\$[***]	\$[***]	\$[***]	\$[***]
11. [***]	\$[***]	\$[***]	\$[***]	\$[***]
12. [***]	\$[***]	\$[***]	\$[***]	\$[***]
13. [***]	\$[***]	\$[***]	\$[***]	\$[***]
14. [***]	\$[***]	\$[***]	\$[***]	\$[***]
15. [***]	\$[***]	\$[***]	\$[***]	\$[***]
16. [***]	\$[***]	\$[***]	\$[***]	\$[***]
17. [***]	\$[***]	\$[***]	\$[***]	\$[***]
18. [***]	\$[***]	\$[***]	\$[***]	\$[***]

	10.4.3	Additional	Milestone	Payment.	For	each	Janssen	Antigen,	in	consideration	of	Fate's
performance in ac	chieving the	e following even	ts, Janssen	shall pay to	Fate 1	the co	respondi	ng amoun	t set	t forth in the t	able	below
(for each Janssen	Antigen, th	e " <mark>Additional M</mark>	lilestone Pa	nyment") if	[***]							

(a)	)	***

(b) [\*\*\*<sup>-</sup>]

(c) [\*\*\*<sup>-</sup>]

(d) [\*\*\*<sup>3</sup>

(e) [\*\*\*<sup>\*</sup>

(f) [\*\*\*].

If each of the events described in clause [\*\*\*] above occurs with respect to a Janssen Antigen, then (i) Janssen shall pay to Fate the Additional Milestone Payment corresponding to such Janssen Antigen not later than [\*\*\*] days after Fate delivers an invoice to Janssen after the occurrence of all such events and (ii) ARTICLE 6 shall no longer apply with respect to any Licensed Products with respect to such Janssen Antigen.

[\*\*\*]

Each Additional Milestone Payment under this Section 10.4.3 shall be non-refundable and non-creditable, and shall be payable [\*\*\*].

	Janssen	Janssen	Janssen	Janssen
	Antigen 1	Antigen 2	Antigen 3	Antigen 4
Additional Milestone Payment	\$[***]	\$[***]	\$[***]	\$[***]

### **10.4.4 Milestone Conditions.**

(a) The milestone payments under this Section 10.4 shall be non-refundable and non-creditable. Payments for Clinical Development Milestone Events (i.e., milestones #1, #2 and #3) shall be payable [\*\*\*]. Payments for Regulatory Milestone Events (i.e., milestones #4 to #21) shall be payable no more than once for each Licensed Product that achieves such milestone event, regardless of the number of times such Licensed Product achieves such milestone event, but shall be payable for each Licensed Product.

**(b)** If Clinical Development Milestone Event #3 ([\*\*\*]) for a particular Janssen Antigen has not occurred before Regulatory Milestone Event #4 ([\*\*\*]) occurs for such Janssen Antigen, then Clinical Development Milestone Event #3 will be deemed to have occurred on the same date as the occurrence of Regulatory Milestone Event #4.

- (c) With respect to Regulatory Milestone Events #14 through #21, [\*\*\*].
- **(d)** If any of Regulatory Milestone Events [\*\*\*] occurs for a particular Licensed Product and Indication, and payment has not been made for Regulatory Milestone Events [\*\*\*], respectively, or for [\*\*\*], in each case for the same Licensed Product and Indication, then such applicable payment for [\*\*\*].
- **10.5 Sales Milestones.** Subject to Section 10.8, as part of the royalty report delivered pursuant to Section 10.6.5, Janssen shall notify Fate, with respect to each Janssen Antigen, the first time the Annual Net Sales of Licensed Products with respect to such Janssen Antigen in a Calendar Year by Janssen, its Affiliates and its Sublicensees exceed, in the aggregate, any of the threshold amounts set forth in the applicable column of the table below (each, a "**Sales Milestone Event**"). Net Sales of a particular Licensed Product in a particular country occurring after the expiration of the Royalty Term (but during the Term) for such Licensed Product in such country shall be included in the calculation of Annual Net Sales for purposes of calculating the amount in the first column of the table below in this Section 10.5. Subject to the remainder of this Section 10.5, Janssen shall pay to Fate the corresponding milestone payment in the table set forth below within [\*\*\*] days after the end of the [\*\*\*] during which such Sales Milestone Event is achieved.

Annual Net Sales of all Licensed Products with respect to the applicable Janssen Antigen in	Milestone Payments						
the Territory first exceed:	Janssen Antigen 1	Janssen Antigen 2	Janssen Antigen 3	Janssen Antigen 4			
1. \$[***]	\$[***]	\$[***]	\$[***]	\$[***]			
2. \$[***]	\$[***]	\$[***]	\$[***]	\$[***]			
3. \$[***]	\$[***]	\$[***]	\$[***]	\$[***]			
4. \$[***]	\$[***]	\$[***]	\$[***]	\$[***]			

The milestone payments under this Section 10.5 shall be non-refundable and non-creditable. Each milestone payment under this Section 10.5 shall be payable [\*\*\*]. The Annual Net Sales of all Licensed Products with respect to the same Janssen Antigen shall be aggregated together in the calculation of Annual Net Sales for purposes of this Section 10.5. For clarity, if two or more Sales Milestone Events occur in one Calendar Year, then the milestone payments for all such Sales Milestone Events shall be payable.

## 10.6 Royalty Payments.

10.6.1 Royalty Rate. Subject to the remainder of this Section 10.6 and Section 10.8, in partial consideration of the licenses granted by Fate to Janssen in accordance with Section 5.1.2 of this Agreement, Janssen shall pay to Fate royalties on the aggregate Annual Net Sales of Licensed Products (excluding Profit Share Products) during the applicable Royalty Term by Janssen, its Affiliates and Sublicensees in the Territory during each Calendar Year at the rates set forth in the table below. Annual Net Sales of all Licensed Products (excluding Profit Share Products) that target the same Janssen Antigen shall be aggregated for purposes of calculation of royalties pursuant to this Section 10.6. Net Sales of a particular Licensed Product in a particular country occurring after the expiration of the Royalty Term for such Licensed Product in such country shall be disregarded in the calculation of Annual Net Sales for purposes of calculating the amount in the first column of the table below in this Section 10.6.1.

Aggregate Annual Net Sales of all Licensed Products with respect to the applicable	Royalty Rate						
Janssen Antigen in the Territory (excluding Profit Share Products)	Janssen Antigen 1	Janssen Antigen 2	Janssen Antigen 3	Janssen Antigen 4			
For that portion of Annual Net Sales of such Licensed Products (excluding Profit Share Products) in the Territory in a Calendar Year less than or equal to \$[***]	[***]%	[***]%	[***]%	[***]%			
For that portion of Annual Net Sales of such Licensed Products (excluding Profit Share Products) in the Territory in a Calendar Year greater than \$[***] and less than or equal to \$[***]	[***]%	[***]%	[***]%	[***]%			
For that portion of Annual Net Sales of such Licensed Products (excluding Profit Share Products) in the Territory in a Calendar Year greater than \$[***] and less than or equal to \$[***]	[***]%	[***]%	[***]%	[***]%			
For that portion of Annual Net Sales of such Licensed Products (excluding Profit Share Products) in the Territory in a Calendar Year greater than \$[***]	[***]%	[***]%	[***]%	[***]%			

<b>10.6.2 Royalty Term.</b> For purposes of this Agreement, " <b>Royalty Term</b> " means, with respect to a
Licensed Product in a particular country, the period of time beginning on the date of the First Commercial Sale of such Licensed
Product in such country and ending on the latest of: (i) the expiration of the last-to-expire Product Claim with respect to such
Licensed Product in such country; (ii) the [***] anniversary of such First Commercial Sale in such country; or (iii) the expiration
of Regulatory Exclusivity for such Licensed Product in such country, if any. After the expiration of the Royalty Term for a
Licensed Product in a country, the last paragraph of Section 15.1 shall apply. For the purposes of the definition of Royalty Term,
"Product Claim" means [***]

(a) [\*\*\*]

(b) [\*\*\*]

(c) [\*\*\*]

[\*\*\*]

[\*\*\*]

# 10.6.3 Royalty Reductions.

(a) If, following the [\*\*\*] anniversary of First Commercial Sale of a Licensed Product in a country, such Licensed Product is sold in such country during the Royalty Term at a time when: [\*\*\*], the royalties payable on Net Sales of such Licensed Product in such country in any Calendar Quarter during the applicable Royalty Term shall be reduced to an amount equal to [\*\*\*] of the royalties that would otherwise be payable on Net Sales of such Licensed Product in such country in such Calendar Quarter under Section 10.6.1, as calculated in accordance with Section 10.6.3(d) and subject to the application of the royalty floor under Section 10.6.3(c).

**(b)** If a Licensed Product is sold in a country during the applicable Royalty Term at a time when [\*\*\*], the royalties payable on Net Sales of such Licensed Product in such country in any Calendar Quarter during the applicable Royalty Term shall be reduced to an amount equal to [\*\*\*] of the royalties that would otherwise be payable on Net Sales of such Licensed Product in such country in such Calendar Quarter under Section 10.6.1, as calculated in accordance with Section 10.6.3(d) and subject to the application of the royalty floor under Section 10.6.3(c).

(c) Notwithstanding the foregoing, in no event shall the operation of Section 10.6.3(a) and 10.6.3(b), individually or in combination, with respect to a Licensed Product reduce the royalties owed to Fate for Net Sales of such Licensed Product in any country in a given Calendar Quarter during the applicable Royalty Term to less than [\*\*\*] of the amount that would otherwise have been payable pursuant to Section 10.6.1 with respect to such Net Sales of such Licensed Product.

	(d)	If the royalties payable with respect to Net Sales of a Licensed Product in a country in a
-		ion under Section 10.6.3(a) or Section 10.6.3(b), the royalties payable with respect to such
Net Sales shall be calcula	ted as follows	3:

(i) First, determine the aggregate Net Sales of such Licensed Product in such country during such Calendar Quarter that occurred during the applicable Royalty Term (the "Quarterly Net Sales").

(ii) Second, determine the Effective Royalty Rate for the applicable Janssen Antigen and applicable Calendar Quarter. The "**Effective Royalty Rate**" means, with respect to a particular Janssen Antigen and a particular Calendar Quarter, the amount (expressed as a percentage) equal to  $A \div B$  (i.e. A divided by B), where:

(1) A = Aggregate amount of royalties payable under Section 10.6.1 applying the relevant royalty tiers, on aggregate Annual Net Sales of Licensed Products with respect to the applicable Janssen Antigen in the Territory during such Calendar Quarter before applying any reductions under Section 10.6.3(a) or 10.6.3(b); and

(2) B = Aggregate Annual Net Sales of Licensed Products with respect to the applicable Janssen Antigen in the Territory during such Calendar Quarter (excluding any Net Sales of such Licensed Products that occurred after the expiration of the applicable Royalty Term).

(iii) Third, multiply [\*\*\*] by [\*\*\*] to determine the royalties that would have been payable on the Quarterly Net Sales pursuant to Section 10.6.1 if no reduction applied under Section 10.6.3(a) or Section 10.6.3(b) (the "Unadjusted Quarterly Royalties").

**(iv)** Last, reduce the Unadjusted Quarterly Royalties to the amount specified in Section 10.6.3(a) or Section 10.6.3(b), as applicable.

# **10.6.4** Third Party License Payments.

- (a) [\*\*\*]
- **(b)** [\*\*\*]
- (c) [\*\*\*]

**10.6.5 Royalty Payment Reports.** Commencing with the First Commercial Sale of a Licensed Product by Janssen or its Affiliates or Sublicensees in the Territory, Janssen shall, within [\*\*\*] days after the end of each [\*\*\*], deliver a final written report to Fate [\*\*\*]. Simultaneously with the delivery of each such final report, Janssen shall pay to Fate the total royalties, if any, due to Fate for the period of such report. If no royalties or payments for Sales Milestone Events are due, Janssen shall so report. All reports delivered by Janssen under this Section shall be Confidential Information of Janssen.

### 10.7 CMC Development Costs.

- **10.7.1** As consideration for Fate's conduct of the CMC Development Plan activities for a Licensed Collaboration Candidate and Licensed Products containing such Licensed Collaboration Candidate, Janssen shall reimburse Fate for all CMC Development Costs incurred by Fate and its Affiliates on the terms set forth in this Section.
- 10.7.2 Within [\*\*\*] days after the end of each [\*\*\*] after the JMC approves a CMC Development Plan for a Licensed Collaboration Candidate under Section 9.1.2, Fate shall submit to Janssen a report, in a format established by the Parties, of all CMC Development Costs incurred by Fate and its Affiliates to conduct activities under such CMC Development Plan during such [\*\*\*] (the "CMC Development Cost Report"). Within [\*\*\*] days following the receipt of the CMC Development Cost Report, Janssen shall have the right to request reasonable additional information, including documentation of Out-of-Pocket Expenses, related to Fate's and its Affiliates' CMC Development Costs during such [\*\*\*]. Janssen shall pay Fate an amount equal to the CMC Development Costs reported in the CMC Development Cost Report within [\*\*\*] days after the end of the applicable [\*\*\*]; provided, however, that CMC Development Costs incurred in performing activities under such CMC Development Plan that exceed the total amount set forth in the applicable CMC Development Budget in the applicable Calendar Year-to-date period shall be included in the calculation of CMC Development Costs to be reimbursed by Janssen only to the extent such excess CMC Development Costs do not exceed [\*\*\*] of the total amount set forth in such CMC Development Budget in the applicable Calendar Year-to-date period in accordance with such CMC Development Budget for such Calendar Year.
- **10.7.3** Janssen shall bear, and shall be fully and solely responsible for, all costs incurred by Janssen and its Affiliates under each CMC Development Plan.
- **10.8 Payments After Fate Exercises the Fate Opt-In Option.** In the event Fate exercises the Fate Opt-In Option with respect to a Profit Share Product pursuant to Section 6.3, ARTICLE VI of the Profit Share Product Exhibit shall apply as follows during the Profit Share Term:
- **10.8.1 Regulatory Milestone Payments and Events**. Section 10.4.2 shall not apply to the Profit Share Product, and instead Section 6.1 of the Profit Share Product Exhibit shall apply.
- **10.8.2 Sales Milestone Payments**. Section 10.5 shall not apply to the Profit Share Product or, following the date of First Commercial Sale of such Profit Share Product, any Related Licensed Products, and instead Section 6.2 of the Profit Share Product Exhibit shall apply.
- **10.8.3 Shared Development Costs, U.S. Pre-Tax Profits and Losses**. Janssen shall not be solely responsible for the costs and expenses of Developing and Commercializing the Profit Share Product, and instead Sections 6.3 and 6.4 of the Profit Share Product Exhibit shall apply.
- **10.8.4 Territory Royalties**. Section 10.6.1 shall not apply to the Profit Share Product, and instead Section 6.5 of the Profit Share Product Exhibit shall apply.

- **10.8.5 CMC Development Costs**. Section 10.7 shall not apply to the Profit Share Product, and instead Section 6.3 of the Profit Share Product Exhibit shall apply.
- **10.8.6 Other Financial Provisions**. The other provisions of ARTICLE VI of the Profit Share Product Exhibit shall apply.

### 10.9 Manner of Payment.

- **10.9.1 Payment Instruction.** All payments to be made by a Party hereunder shall be made in Dollars by wire transfer to the bank account as shall be designated by the Party receiving the payment.
- **10.9.2 Exchange Rate**. If any amounts that are relevant to the determination of amounts to be paid under this Agreement or any calculations to be performed under this Agreement are received or paid or initially reported in a currency other than U.S. Dollars, then such amounts shall be converted to their U.S. Dollar equivalent as follows:
  - (a) [\*\*\*]
  - (b) [\*\*\*].
- **10.9.3 Late Payment**. If either Janssen or Fate shall fail to make a timely payment pursuant to this ARTICLE 10 or any other provision of this Agreement, any such payment that is not paid on or before the date such payment is due under this Agreement shall bear interest at a rate per annum equal to [\*\*\*] or the maximum rate allowable by applicable Law, whichever is lower.
- **10.10 Records**. Each Party shall keep, and cause its Affiliates and Sublicensees to keep, complete and accurate records of the items underlying Research Costs, CMC Development Costs and Net Sales, and with respect to each Profit Share Product, Shared Development Costs, Allowable Expenses and Other Income, and any other elements required to prepare the reports or calculate payments required by under this Agreement or, with respect to each Profit Share Product, the Profit Share Product Exhibit. Such records must be retained for a period of [\*\*\*] months following the relevant reporting period.

### **10.11** Audits.

**10.11.1** Each Party will have the right at its own expense to have an independent, certified public accountant of nationally recognized standing, selected by such Party and reasonably acceptable to the other Party, review any records of the other Party and its Affiliates that are required to be kept pursuant to Section 10.10 in the location(s) where such records are maintained by the other Party or its Affiliates upon [\*\*\*] days prior written notice and during normal business hours and under obligations of confidence, for the sole purpose of verifying the basis and accuracy of payments made under this Agreement or the Profit Share Product Exhibit, within the prior [\*\*\*]-month period. Audits may not be conducted by a Party under this Section more than once every [\*\*\*], and an audit of the records relating to a particular Calendar Year may be conducted not more than once.

- 10.11.2 The report of the independent certified public accountant shall be shared with the audited Party before distribution to the auditing Party so that the audited Party can provide the independent public accountant with justifying remarks for inclusion in the report before sharing the conclusions of such independent public audit with the auditing Party. The final audit report will be shared with the auditing and audited Party at the same time and shall specify whether the amounts paid to the auditing Party during the audited period were correct or, if incorrect, the amount of any underpayment or overpayment. The audit report shall only contain the information relevant to support the statement as to whether the amounts due under this Agreement were calculated and paid accurately and shall not include any confidential information (or additional information that is ordinarily not included in the reports to the auditing Party) disclosed to the auditor during the course of the audit.
- 10.11.3 If the review of such records reveals that the audited Party has failed to accurately report information pursuant to the relevant provisions of this Agreement or the Profit Share Product Exhibit or make any payment (or portion thereof) required under this Agreement, then the audited Party shall pay, within [\*\*\*] days after receipt of the final audit report by the audited Party, to the auditing Party any underpaid amounts due under this Agreement, together with interest calculated in the manner provided in Section 10.9.3. If any such discrepancies resulted in an underpayment or overpayment, as the case may be, of amounts due under this Agreement greater than [\*\*\*] of the amounts actually due for the applicable Calendar Year, the audited Party shall pay all reasonable costs incurred in conducting such review. If the audited Party disagrees with the findings of the audit report, the Parties will first seek to resolve the matter between themselves, and in the event they fail to reach agreement, the dispute resolution provisions set forth in ARTICLE 16 shall apply.

### 10.12 Taxes.

- **10.12.1** Except as otherwise provided in this Agreement, each Party will make all payments to the other Party under this Agreement without deduction or withholding for Taxes except to the extent that any such deduction or withholding is required by law in effect at the time of payment.
- 10.12.2 Any Tax required to be withheld on amounts payable under this Agreement will be paid by the paying Party on behalf of the recipient Party to the appropriate governmental authority, and the paying Party will furnish the recipient Party with proof of payment of such Tax. Any such Tax required to be withheld will be an expense of and borne by the recipient Party. If any such Tax is assessed against and paid by the paying Party then the recipient Party will indemnify and hold harmless the paying Party from and against such Tax. Notwithstanding the foregoing, the Parties acknowledge and agree that if the paying Party (or its assignee pursuant to Section 17.4) is required by applicable Law to withhold Taxes in respect of any amount payable under this Agreement, and if such withholding obligation arises solely as a result of a Withholding Tax Action and such withholding Taxes exceed the amount of withholding Taxes that would have been applicable if such Withholding Tax Action had not occurred, then notwithstanding anything to the contrary herein, any such amount payable shall be increased to take into account such increased withholding Taxes as may be necessary so that, after making all required withholdings the recipient Party receives an amount equal to the sum it would have received had no such Withholding Tax Action occurred. [\*\*\*\*]
- **10.12.3** The Parties will cooperate with respect to all documentation required by any taxing authority or reasonably requested by either Party to secure a reduction in the rate of applicable withholding Taxes.

# ARTICLE 11 INTELLECTUAL PROPERTY

### 11.1 Inventions.

11.1.1 Inventorship. The Parties agree that ownership of inventions conceived, developed or reduced to practice in the course of activities performed under this Agreement, together with all intellectual property rights therein (collectively, "Inventions") shall be consistent in the Territory with ownership as determined by application of U.S. patent Laws pertaining to inventorship. In no event shall either Party be liable to the other Party for compensation to any inventors for Inventions conceived, developed or reduced to practice by director(s), officer(s) or employee(s) of the other Party regardless of which Party has ownership rights to such Inventions pursuant to this Section 11.1.

## 11.1.2 Ownership.

- (a) Subject to Section 11.1.2(b), all Inventions conceived, developed or reduced to practice solely by or on behalf of Janssen shall be solely owned by Janssen, all Inventions conceived, developed or reduced to practice solely by or on behalf of Fate shall be solely owned by Fate, and all Inventions conceived, developed or reduced to practice jointly by or on behalf of Janssen and Fate shall be jointly owned by Janssen and Fate.
- **(b)** Notwithstanding Section 11.1.2(a), the ownership of the following Inventions shall be as follows, regardless of the inventorship of such Inventions between the Parties:
  - **(i)** Fate shall solely own any Invention that is [\*\*\*]; and
  - (ii) Janssen shall solely own any Invention that is [\*\*\*].
- (c) In the case of Inventions jointly owned by Janssen and Fate ("Joint Inventions"), and any Patents that claim or disclose such Joint Inventions ("Joint Patents"), each Party shall own an equal and undivided interest in the Joint Inventions and Joint Patents, with the right to practice, license and exploit the Joint Inventions and Joint Patents, without the duty or accounting or seeking consent from the other Party, subject to any exclusive licenses granted herein and in a manner not inconsistent with this Agreement.
- Affiliates to so disclose, the conception, development or reduction to practice of any Invention during the Term of this Agreement. Each Party shall cause its Affiliates, employees, directors and officers to so assign to such Party, such person's or entity's right, title and interest in and to any such Inventions, and intellectual property rights therein, as is necessary to enable such Party to fully effect the ownership of such Inventions, and intellectual property rights therein, as provided for in Section 11.1.2. Each Party shall include provisions in its relevant agreements with Third Party contractors performing obligations on its behalf pursuant to this Agreement and with Sublicensees, that effect the intent of this ARTICLE 11. Each Party shall, and shall cause its Affiliates, employees, directors, and officers, Sublicensees and Third Party contractors, in each case to cooperate with such other Party and take all reasonable additional actions and execute such agreements, instruments and documents as may be reasonably required to perfect such other Party's right, title and interest in and to Inventions, and intellectual property rights therein, as set forth in this Section 11.1. Regardless of the foregoing and any provision of this Section 11.1, a Party engaging a CRO (or clinical trial site) for the conduct of Clinical Trials or a CMO may agree to such terms as to the ownership of intellectual property, including Patents, as is reasonable under the circumstances and/or customary.

### 11.2 Patent Prosecution.

## 11.2.1 Fate Patents.

- (a) The Parties recognize that it is their shared goal to obtain the broadest patent coverage available with regard to the Fate Product Patents, consistent with the goal of obtaining patents that are valid and enforceable as against Third Parties. The Parties recognize the value and importance of Fate's knowledge, prior experience and expertise with the patent prosecution of the Fate Product Patents. Janssen acknowledges that there will be multiple licensees of certain Fate Product Patents and that Fate has the responsibility to determine how best to conduct patent prosecution of the Fate Product Patents for the benefit of all licensees, including Janssen and Fate's Third Party licensees. Fate acknowledges that coordination of prosecution of patents and patent applications within the Fate Research Patents and Fate Product Patents is consistent with the foregoing goals and responsibilities.
- (b) Subject to the terms and conditions of the Existing Agreements, Fate shall be responsible, using patent counsel used by Fate as of the Effective Date or selected by Fate after the Effective Date and reasonably acceptable to Janssen (for clarity, [\*\*\*] for the preparation, filing, prosecution (including any interferences, oppositions, reissue proceedings, reexaminations and similar proceedings) and maintenance (collectively, "**Prosecution**") of Fate Research Patents and Fate Product Patents (collectively, "**Fate Patents**"), including those claiming Inventions to be solely owned by Fate under this Agreement. Fate shall keep Janssen reasonably informed with respect to such Prosecution activities, but Fate shall have the right to take such reasonable acts in connection therewith as Fate, in its sole discretion, deems appropriate, *provided* Fate is acting in good faith to obtain and maintain Fate Product-Specific Patents effective for market exclusivity of Licensed Products.
- **(c)** With respect to those Fate Patents that are owned solely by Fate and that [\*\*\*] ("**Fate Product-Specific Patents**"), Fate shall promptly provide Janssen with copies of all correspondence to or from the USPTO, EPO and equivalent patent offices in foreign jurisdictions, relating to such Fate Product-Specific Patents. Fate shall take into account and consider in good faith Janssen and its interests and requests regarding the filing, prosecution and maintenance of Fate Product-Specific Patents under this Section; *provided*, *however*, that Fate shall have the right to take such reasonable acts in connection therewith as Fate, in its sole discretion, deems appropriate, *provided* Fate is acting in good faith to obtain and maintain Fate Product-Specific Patents effective for market exclusivity of Licensed Product.
- (d) If Fate, prior or subsequent to filing any Patent that would constitute Fate Product-Specific Patents, elects not to file, prosecute or maintain such Patent, Fate shall give Janssen notice thereof within a reasonable period prior to allowing such Patent to lapse or become abandoned or unenforceable, and [\*\*\*] Fate shall (and shall cause its outside counsel to) prepare and file Fate Product-Specific Patents as instructed by Janssen, including in countries requested by Janssen to the extent permitted by applicable Law. The Parties understand that [\*\*\*]. In such case, Fate and Janssen shall reasonably cooperate to [\*\*\*]; provided, however, that, [\*\*\*], or (B) if a claim of a Patent owned by Janssen which claims [\*\*\*]. In the circumstance where [\*\*\*]. Notwithstanding such [\*\*\*] for all purposes of this Agreement, including rights of enforcement and licenses [\*\*\*].

(e) As between the Parties, Fate shall be solely responsible for all costs and expenses Fate incurs in connection with the Prosecution of the Fate Patents that are not Fate Product-Specific Patents. Janssen shall reimburse Fate for all reasonable out-of-pocket costs incurred by Fate in connection with the Prosecution of the Fate Product-Specific Patents; *provided*, *however*, that (i) at any time Janssen may elect not to be responsible for such costs, in which case such applicable Fate Product-Specific Patent will no longer be included in any licenses granted to Janssen hereunder and (ii) such costs will be included in Allowable Expenses to the extent related to Profit Share Products in the U.S.

Janssen Patents. Janssen shall be solely responsible for the Prosecution of any Patent that is solely owned by Janssen, including those filed by Janssen covering its solely-owned Inventions; provided, however, that Janssen shall not file any Patent disclosing or claiming specifically any Collaboration Candidate or corresponding Precursor iPSC, Master iPSC Bank, CD34 Composition, CD34 Composition, CAR-T Cells or CAR-NK Cells unless such Collaboration Candidate is a Licensed Collaboration Candidate (or a Discontinued Collaboration Candidate or Equivalent licensed to Janssen pursuant to Section 5.1.3). With respect to any such Patents solely owned by Janssen that claim a Profit Share Product (or any precursor or component thereof) or its manufacture or use ("Janssen Profit Share Patents"), Janssen shall keep Fate reasonably informed with respect to its Prosecution activities, and Fate may consult with Janssen and provide advice to Janssen regarding such Prosecution activities, but Janssen shall have the right to take such reasonable acts in connection therewith as Janssen deems appropriate, in its sole discretion, provided Janssen is acting in good faith to obtain and maintain Janssen Profit Share Patents effective for market exclusivity of Profit Share Products. Janssen shall promptly provide Fate with copies of all correspondence to or from the USPTO, EPO and equivalent patent offices in foreign jurisdictions, relating to such Janssen Profit Share Patents. Janssen shall take into account and consider in good faith Fate and its interests and requests regarding the filing, prosecution and maintenance of Janssen Profit Share Patents under this Section. If Janssen, prior or subsequent to filing any Patent that would constitute any Janssen Profit Share Patents, elects not to file, prosecute or maintain such Patent in any of the Major Markets, Janssen shall give Fate notice thereof within a reasonable period prior to allowing such Patent to lapse or become abandoned or unenforceable, and Fate shall thereafter have the right, but not the obligation, to prepare, file, prosecute and maintain such Janssen Profit Share Patents. In the event that Fate assumes responsibility for such Janssen Profit Share Patents pursuant to this Section, Janssen shall reasonably cooperate with Fate in maintaining and prosecuting such patent rights. The reasonable out-of-pocket costs incurred by Janssen in connection with Prosecuting the Janssen Profit Share Patents in the U.S. will be included in Allowable Expenses.

### 11.2.3 Joint Patents.

- Upon receiving notice of the creation of Joint Inventions, Fate shall have the first right, but not the obligation, to be responsible for Prosecuting any Joint Patents using outside legal counsel selected by Fate and reasonably approved by Janssen. If Fate elects to be responsible for such activities, Fate shall Prosecute any Joint Patents filed in the Territory, in the names of both Fate and Janssen. Fate shall provide Janssen an opportunity to review and comment on material documents related to such Prosecution in accordance with this Section 11.2.3, which comments Fate shall consider in good faith. If Fate decides not to be responsible for Prosecuting any particular Joint Patent in any particular country, Fate shall notify Janssen in writing and Janssen shall have the right, but not the obligation, to be responsible for such activities in such country. In this case, Janssen may Prosecute such Joint Patents in such country in the names of both Fate and Janssen, and Janssen shall provide Fate an opportunity to review and comment on material documents related to such Prosecution in accordance with this Section 11.2.3, which comments Janssen shall consider in good faith. Each Party shall at its own cost, sign, or use [\*\*\*] Efforts to have signed, all legal documents necessary to Prosecute Joint Patents. Each Party shall fully cooperate with the other Party in providing the other Party with necessary information in its possession for such Prosecution.
- Prosecution of Joint Patents ("Joint Patent Costs"). The Party who is responsible for the Prosecution of the Joint Patent shall, through its patent counsel, if applicable, invoice the other Party for its share of such Joint Patent Costs within [\*\*\*] days after the end of the month during which such Joint Patent Costs were incurred and the other Party shall pay its share of such Joint Patent Costs to the applicable Party or its patent counsel within [\*\*\*] days after receipt of such invoice. Notwithstanding this Section 11.2.3, if a Party does not wish to bear Joint Patent Costs with respect to a Joint Patent in a country, such Party may, by providing [\*\*\*] days prior written notice to the other Party, terminate its obligation to pay such Joint Patent Costs. In this case, such Party shall promptly assign all of its right, title and interest in and to such Joint Patent in such country to the other Party upon such other Party's written request at such other Party's cost; *provided*, *however*, that such Joint Patent shall cease being a Joint Patent (but remain a Research Program Inventions and, as such, subject to the Research Program Inventions Cross License) and shall be deemed either a Fate Patent solely owned by Fate if Janssen is the assigning Party or a Patent solely owned by Janssen if Fate is the assigning Party.
- (c) Subsection (a) above notwithstanding, with respect to those Joint Patents that (i) Cover the composition of matter of the Licensed Collaboration Candidate or the Licensed Product containing the Licensed Collaboration Candidate, or of the Precursor iPSC, Master iPSC Bank or CD34 Composition corresponding to such Licensed Collaboration Candidate, and (ii) definitively recite (in the claims) a Janssen Antigen Binding Domain or any Close Homolog thereof ("Joint Product-Specific Patents"), the Parties will treat a Joint Product-Specific Patent under this Section 11.2.3 as if it were in all respects a Fate Product-Specific Patent.

11.2.4 Cooperation. Each Party agrees to reasonably cooperate with the other with respect to the preparation, filing, prosecution, validation, extension and maintenance of Patents pursuant to this Section 11.2. At the request of the other Party, the Party responsible for preparing, filing, prosecuting, validating, maintaining and extending a Patent shall make reasonable efforts to separately prosecute subject matter solely related to Fate Product-Specific Patents, Joint Product-Specific Patents, and Janssen Profit Share Patents separate from other subject matter which may be disclosed or claimed in any Patent hereunder, to the extent it may reasonably do so without jeopardizing or impairing any such patent rights. Each Party's rights to Prosecute a Patent pursuant to this Section 11.2 shall be subject to the applicable provisions of any agreements between the Party Controlling such Patents and its licensor. All information exchanged between the Parties under this Section 11.2 pertaining to any Fate Patent shall be deemed Confidential Information exchanged between the Parties under this Section 11.2 pertaining to any Janssen Patent shall be deemed Confidential Information of Janssen, and all information exchanged between the Parties under this Section 11.2 pertaining to any Joint Patents shall be deemed Confidential Information of both Parties.

### 11.3 Patent Enforcement.

Collaboration Candidate, Fate or Janssen becomes aware of any actual infringement or threat of infringement of any Fate Product Patent, Janssen Profit Share Patent or Joint Patent by means of the sale, including the manufacture for sale, by a Third Party of a Third Party Competitive Product or a Biosimilar Product with respect to any Licensed Collaboration Candidate or any Licensed Product containing a Licensed Collaboration Candidate, or of the Precursor iPSC Bank, Master iPSC Bank or the CD34 Composition corresponding to a Licensed Collaboration Candidate, or if any Fate Product Patent, Janssen Profit Share Patent or Joint Patent is challenged in any action or proceeding (other than any oppositions, cancellations, interferences, reissue proceedings or reexaminations, which are addressed above) as invalid or unenforceable (such infringements and challenges collectively, "Product Infringement" with respect to such Licensed Collaboration Candidate or Licensed Product containing such Licensed Collaboration Candidate, or the Precursor iPSC, Master iPSC Bank or the CD34 Composition corresponding to such Licensed Collaboration Candidate), such Party shall notify the other Party promptly, and following such notification, the Parties shall confer. As used in this Section 11.3.1, a "Third Party Competitive Product" means [\*\*\*], in each case expressing a CAR that is Directed to [\*\*\*\*].

# 11.3.2 Enforcement of Fate Product-Specific Patents, Janssen Profit Share Patents, and certain Joint Patents.

(a) Janssen shall have the first right to institute infringement suits or take other action under the Fate Product-Specific Patents and Joint Product-Specific Patents, and under the Janssen Profit Share Patents, in each case to the extent the same is directed to a Product Infringement, including defense of a declaratory judgment action with respect to a potential Product Infringement (whether prior to or after the First Commercial Sale of such Licensed Product) (each, an "Infringement Action"), and in each case Janssen shall have the right to institute such suit or other appropriate action in the name of Fate or of Janssen, or in the names of both of them. For clarity, Janssen shall have the right to institute infringement suits or take other action under Patents owned or controlled by Janssen (not Joint Patents) covering Inventions, Collaboration Candidates, a Licensed Collaboration Candidate or a Licensed Product containing such Licensed Collaboration Candidate, or the Precursor iPSC, Master iPSC Bank or the CD34 Composition corresponding to such Licensed Collaboration Candidate that are not Janssen Profit Share Patents, *provided* that Janssen shall keep Fate reasonably updated on the progress of any such suits or actions.

(b) In the event that Janssen institutes or undertakes an Infringement Action in accordance with Section 11.3.2(a) Fate shall cooperate fully with Janssen in its efforts to protect such patent rights and shall agree to be a party in any suit, if required, in each case with respect to such Infringement Action, in each case at Janssen's sole expense. Further, Fate shall have a right, in Fate's sole discretion and at Fate's expense, to join or otherwise participate in such Infringement Action with legal counsel selected by Fate. Janssen shall notify and keep Fate apprised in writing of such Infringement Action and shall consider and take into account Fate's reasonable interests and requests regarding such Infringement Action.

(c) In the event that Janssen does not institute or undertake an Infringement Action in accordance with Section 11.3.2(a) for a period of [\*\*\*] days after being requested by Fate to do so, or (if sooner) at least [\*\*\*] days prior to the last date such Infringement Action may be brought, Fate may institute or undertake and thereafter control such Infringement Action. In such event, Fate shall have the right, but not the obligation, to institute or undertake such suit or other appropriate Infringement Action in the name of Fate or of Janssen or in the names of both of them. Janssen shall cooperate fully with Fate in its efforts to protect such patent rights and shall agree to be a party in any suit, if required, in each case with respect to such Infringement Action, in each case at Fate's sole expense.

## 11.3.3 Enforcement of Fate Patents other than Fate Product-Specific Patents and certain Joint

### Patents.

(a) Fate shall have the first right to institute infringement suits or take other actions directed to a Product Infringement of (i) those Fate Patents that are not Fate Product-Specific Patents and (ii) Joint Patents other than Joint Product-Specific Patents, including defense of a declaratory judgment action with respect to a potential Product Infringement, and in each case Fate shall have the right to institute such suit or other appropriate action in the name of Fate or of Janssen, or in the names of both of them. Janssen shall cooperate fully with Fate in its efforts to protect such patent rights and shall agree to be a party in any suit, if required, at Fate's sole expense. Fate shall notify and keep Janssen apprised in writing of such action and shall consider and take into account Janssen's reasonable interests and requests regarding such action.

(b) In the event that Fate does not institute or undertake an action in accordance with Section 11.3.3(a) for a period of [\*\*\*] days after being requested by Janssen to do so, or (if sooner) at least [\*\*\*] days prior to the last date such action may be brought, then upon Fate's written consent, which may be granted or withheld in Fate's sole discretion, Janssen may institute or undertake and thereafter control such action, in the name of Fate or of Janssen or in the names of both of them. If Fate consents to such action, Janssen shall cooperate fully with Fate in its efforts to protect such patent rights and shall agree to be a party in any suit, if required, at Janssen's sole expense.

Conduct of Patent Litigation Under the Biologics Price Competition and Innovation 11.3.4 **Act.** If either Party receives a copy of an application submitted to the FDA under subsection (k) of Section 351 of the PHSA or equivalent in any other jurisdiction pertaining to and naming a Licensed Product as a reference product (a "Biosimilar **Application**") or otherwise becomes aware that such a Biosimilar Application has been filed (such as in an instance described in Section 351(l)(9)(C) of the PHSA), such Party shall, within [\*\*\*] Business Days, notify the other Party so that the other Party may seek permission to view the application and related confidential information from the filer of the Biosimilar Application under Section 351(l)(1)(B)(iii) of the PHSA or equivalent in any other jurisdiction. If either Party receives any equivalent or similar certification or notice in any other jurisdiction, such Party shall, within [\*\*\*] Business Days, notify and provide the other Party with copies of such communication. Regardless of the Party that is the "reference product sponsor" for purposes of such Biosimilar Application, [\*\*\*] shall have the sole right, but not the obligation, to initiate an Infringement Action against the filer of the Biosimilar Application to enforce any [\*\*\*] Product-Specific Patent or any Joint Product-Specific Patent, including whether or not to utilize, in whole or in part, the procedures provided in Section 351 of the PHSA or equivalent in any other jurisdiction. If [\*\*\*] institutes any such Infringement Action, then [\*\*\*] shall join as a party to such claim, suit or proceeding requiring it as a party at [\*\*\*] sole cost and expense. With respect to a [\*\*\*] Patent that is not a [\*\*\*] Product-Specific Patent or Joint Patents other than Joint Product-Specific Patents and to the extent the action is under this Section, [\*\*\*] shall determine whether any infringement suit or other action shall be initiated, and if so, which Party shall have the right to initiate and undertake such action and other matters pertaining to such action.

11.3.5 Cooperation. In any Infringement Action brought under this Section 11.3 in any jurisdiction, each Party shall reasonably cooperate with each other, in good faith, relative to the other Party's efforts to protect the patent rights and shall agree to be a party to such Infringement Action, if necessary. Notwithstanding anything to the contrary in this Section 11.3, neither Party shall settle or compromise any related defense or infringement suit brought under the Fate Product-Specific Patents, Janssen Profit Share Patents or Joint Patents pursuant to this Section 11.3 without the prior written consent of the other Party, which consent shall not be unreasonably withheld. Furthermore, each Party shall provide the other Party with reasonable prior notice and opportunity to review and comment and shall consider in good faith all reasonable comments from the other Party on any proposed arguments asserted or to be asserted in any enforcement action under this Section 11.3.

**11.3.6 Recoveries.** With respect to any Infringement Action or other action against a Product Infringement initiated pursuant to this Section 11.3, any recovery obtained as a result of any such proceeding, by settlement or otherwise, shall be applied in the following order of priority:

- (a) [\*\*\*]
- **(b)** [\*\*\*]

- 11.3.7 Product Infringement with respect to Profit Share Product. Notwithstanding anything to the contrary in this Section 11.3, in the case of any Product Infringement with respect to any Profit Share Product in the U.S., the Out-of-Pocket Expenses incurred in connection with any action against such Profit Share Product in accordance with this Section 11.3, and any recoveries, will be included in the Allowable Expenses and Net Sales, respectively, with respect to such Profit Share Product.
- **11.3.8 Upstream Limitations.** Each Party's rights to enforce or defend a Fate Product Patent or Joint Patent against a Product Infringement pursuant to this Section 11.3 shall be subject to the applicable provisions of any agreements between the Party Controlling such Patents and its licensor.
- 11.3.9 Other Enforcement of Fate Patents, Janssen Patents and Joint Patents. As between the Parties, Fate shall have the sole right, in its sole discretion, to enforce any Fate Patent that is not a Fate Product-Specific Patent against any infringement that is not a Product Infringement and to retain all related recoveries, and Janssen shall have the sole right, in its sole discretion, to enforce any Patent owned or controlled by Janssen that is not a Janssen Profit Share Patent against any infringement that is not a Product Infringement and to retain all related recoveries. If there is any infringement of any Joint Patents that is not a Joint Product-Specific Patent and that is not a Product Infringement, then each Party shall have the right to enforce such Joint Patents at its sole expense.
- **11.4 Patent Term Extension**. [\*\*\*] shall have the sole discretion, after consultation with [\*\*\*], to determine which [\*\*\*] Product-Specific Patents or Joint Patents, if any, are extended with respect to any Licensed Product pursuant to U.S. Drug Price Competition and Patent Term Restoration Act of 1984, the Supplementary Certificate of Protection of Member States of the EU and other similar measures in other jurisdictions worldwide. Upon [\*\*\*] request, the Parties will discuss whether any other Fate Patent will be extended with respect to any Licensed Product, which extension may be made only with [\*\*\*] written consent, which shall not be unreasonably withheld. Fate and Janssen shall each cooperate and use reasonable efforts to gain any such patent term extension permitted under this Section 11.4. All filings for such extensions shall be made by the Party responsible for the prosecution of such patent rights.
- **11.5 Regulatory Data Protection.** To the extent required by or permitted by Law, Fate and Janssen shall each cooperate with one another and shall use [\*\*\*] Efforts to promptly, accurately and completely list, with the applicable Regulatory Authorities during the Term, all applicable Licensed Products that a Party intends to, or has begun to, Commercialize and that, in case of the United States, have become the subject of an application for a Marketing Approval submitted to FDA, such listings to include all so called "**Purple Book**" listings of biologic products by both the Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) required under section 351(a) of the Public Health Service Act (PHS Act) and any foreign equivalent, and will cooperate and use [\*\*\*] Efforts to secure all applicable exclusivity protection available as a Biologic Reference Product under the Purple Book.

## 11.6 Patent Invalidity Claims.

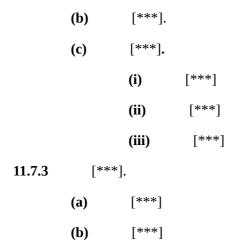
- **11.6.1 Right to Respond.** If during the Term a Third Party initiates a patent opposition, reexamination, or other proceeding in the US Patent Office, European Patent Office or foreign equivalent, asserting that Fate Product-Specific Patents or Joint Product-Specific Patents are invalid or otherwise unenforceable (an "**Invalidity Claim**"), the Parties shall treat this as a Prosecution in accordance with Section 11.2.1(b) or Section 11.2.3(a). For the avoidance of doubt, any response to a Third Party declaratory judgment action with respect to such Fate Product-Specific Patent claims or Joint Product-Specific Patent claims or a counterclaim of invalidity or unenforceability of such claims made in the context of an Infringement Action, to the extent the same pertains to a potential Product Infringement, shall be deemed an Infringement Action and shall be governed by Section 11.3.
- 11.6.2 The non-controlling Party shall cooperate with the controlling Party in the preparation and formulation of a response to an Invalidity Claim, and in taking other steps reasonably necessary to respond, to such Invalidity Claim. The controlling Party shall have the sole and exclusive right to select counsel for the response to such Invalidity Claim. The non-controlling Party shall also have the right to participate and be represented relative to such proceeding by its own counsel at its own expense. The controlling Party shall not settle or compromise any Invalidity Claim in a manner that admits the invalidity or unenforceability of any Fate Patents or Joint Patents, or that requires a payment to the Third Party in respect of such Invalidity Claim, without the consent of the other Party, which consent shall not be unreasonably withheld.
- 11.6 Claimed Infringement. Each of the Parties shall promptly notify the other in the event that any Third Party files any suit or brings any other action alleging patent infringement by Janssen or Fate with respect to the Development, Manufacture, Commercialization or use of any Licensed Collaboration Candidate or a Licensed Product containing such Licensed Collaboration Candidate, or of the Precursor iPSC, Master iPSC Bank or the CD34 Composition corresponding to such Licensed Collaboration Candidate (any such suit or other action referred to herein as an "Infringement Claim"). In the event of any Infringement Claim, the Parties shall promptly, and within [\*\*\*] days of written notice from either Party to the other thereof, discuss which Party shall control the response to such Infringement Claim, and if the Parties do not mutually agree upon which Party shall control, then [\*\*\*] shall have the right to control the defense of such Infringement Claim. Upon the request of the Party controlling the response to the Infringement Claim, the other Party shall reasonably cooperate with the controlling Party at the controlling Party's expense in the reasonable defense of such Infringement Claim. The other Party will have the right to consult with the controlling Party concerning any Infringement Claim and to participate in and be represented by independent counsel in any associated litigation at its own expense. [\*\*\*] Notwithstanding the foregoing, (i) no settlement shall be entered into, or accepted, without the prior written consent of the other Party if such settlement would materially adversely affect the rights and benefits of, or impose or adversely affect any obligations on, such other Party, which consent shall not unreasonably be withheld, delayed or conditioned, and (ii) the Parties' rights and obligations under this Section 11.6 will be subject to ARTICLE 14, if applicable.

## 11.7 Third Party Licenses.

- **11.7.1 Existing Agreements.** The Parties agree and understand that Fate has entered into certain agreements under which Fate has been granted a license, prior to the Effective Date, with the rights to sublicense, under certain patents and patent applications included within the Fate Research Patents and Fate Product Patents that are subject to royalty obligations (such agreements collectively, the "**Existing Agreements**"). In accordance with Section 10.6.4, payments under the Existing Agreements [\*\*\*]. The list of Existing Agreements is set forth on **Exhibit 11.7.1**. With respect to each of the Existing Agreements, Fate shall:
- (a) use [\*\*\*] Efforts to maintain in full force and effect such agreement (in accordance with its terms), (including by not assigning such Existing Agreement, or any of its rights thereunder, to a Third Party without the consent of Janssen, not to be unreasonably withheld or delayed, except in connection with a Change of Control transaction), and keep Janssen informed of any material development pertaining thereto that adversely affects the rights granted to Janssen hereunder for so long as such Third Party rights are sublicensed to Janssen in accordance with Section 5.1;
- **(b)** not take any action to terminate, modify, amend or waive any right, to the extent incompatible with the rights sublicensed to Janssen in accordance with Section 5.1;
- (c) not fail to enforce any right, knowingly breach or otherwise take any other action with respect to any such Existing Agreement that would reasonably be expected to materially impact the rights granted to Janssen under this Agreement, without the consent of Janssen, including by failing to comply in all material respects with the terms of such Existing Agreement or by failing to make all payments that become due under such Existing Agreement in accordance with its terms; and
- (d) if Fate or any of its Affiliates receives written notice from the applicable Third Party claiming that Fate or any of its Affiliates has breached or defaulted under, or is in breach of or default under, its obligations under such Existing Agreement, where such Third Party has the right to terminate such agreement if Fate does not timely cure such breach or default, provide a copy thereof to Janssen promptly after receipt and, following consultation with Janssen, consider Janssen's input in good faith and take such reasonable actions as may be reasonably necessary to cure any breach or default.

## 11.7.2 [\*\*\*] or Improved Platform Licenses.

(a) For purposes of this Section 11.7.2, "**Fate Existing Technology**" means Fate's proprietary information, methods, protocols, processes, procedures and technologies relating to[\*\*\*].



11.8 Common Interest Disclosures. With regard to any information, opinions or other materials disclosed pursuant to this Agreement by one Party to the other Party regarding intellectual property or technology owned by Third Parties, Janssen and Fate agree that they have a common legal interest in determining whether, and to what extent, Third Party intellectual property rights may affect the performance of the Research, Development, Manufacturing or Commercialization of a Licensed Collaboration Candidate or a Licensed Product containing such Licensed Collaboration Candidate, or of the Precursor iPSC, Master iPSC Bank or the CD34 Composition corresponding to such Licensed Collaboration Candidate, and have a further common legal interest in defending against any actual or prospective Third Party claims based on allegations of misuse or infringement of intellectual property rights relating to the performance of the Research, Development, Manufacturing or Commercialization of a Licensed Collaboration Candidate or a Licensed Product containing such Licensed Collaboration Candidate, or of the Precursor iPSC, Master iPSC Bank or the CD34 Composition corresponding to such Licensed Collaboration Candidate. Accordingly, Janssen and Fate agree that all such information, opinions and other materials obtained by Janssen and Fate from each other will be used solely for purposes of the Parties' common legal interests with respect to the conduct of this Agreement. All such information, opinions and other materials shall be treated as protected by the attorney-client privilege, the work product privilege, and any other privilege or immunity that may otherwise be applicable. By sharing any such information, opinions and other materials, neither Party intends to waive or limit any privilege or immunity that may apply to the shared information, opinions and other materials. Neither Party shall have the authority to waive any privilege or immunity on behalf of the other Party with respect to such information, opinions and other materials without such other Party's prior written consent. nor shall the waiver of privilege or immunity resulting from the conduct of one Party be deemed to apply against the other Party.

# ARTICLE 12 CONFIDENTIALITY

- **12.1 Nondisclosure**. Each Party agrees that, during the Term and for a period of [\*\*\*] years thereafter, a Party (the "**Receiving Party**") receiving or otherwise in possession of (itself or through its Affiliates) Confidential Information of the other Party (the "**Disclosing Party**") or its Affiliates shall (a) maintain in confidence such Confidential Information using not less than the efforts such Receiving Party uses to maintain in confidence its own confidential information of similar kind and value, which shall not be less than reasonable efforts, (b) not disclose such Confidential Information to any Third Party without the prior written consent of the Disclosing Party, except for disclosures expressly permitted in, and made in accordance with, Section 12.3, 12.5, 12.8.2 or 12.9 and (c) not use such Confidential Information for any purpose except those permitted by this Agreement or internal management and operations directly pertaining to this Agreement (it being understood that this clause (c) shall not create or imply any rights or licenses not expressly granted under this Agreement). Notwithstanding anything to the contrary in this ARTICLE 12, Janssen shall have the right to use and disclose any Fate Confidential Method solely in accordance with Section 5.3.
- **12.2 Exceptions**. The obligations in Section 12.1 shall not apply with respect to any portion of the Confidential Information that the Receiving Party can show by competent evidence:
- **12.2.1** is publicly disclosed by the Disclosing Party or its Affiliates, either before or after it is disclosed to the Receiving Party or its Affiliates under this Agreement;
- **12.2.2** was known to or possessed by the Receiving Party or its Affiliates, without any obligation to the Disclosing Party to keep it confidential or any restriction on its use, prior to disclosure by the Disclosing Party or any of its Affiliates;
- **12.2.3** is subsequently disclosed to the Receiving Party or its Affiliates by a Third Party that, to the Receiving Party's knowledge after due inquiry, is not bound by a duty of confidentiality to the Disclosing Party or its Affiliates or restriction on its use:
- **12.2.4** is published by a Third Party or otherwise becomes publicly available or enters the public domain, either before or after it is disclosed to the Receiving Party or its Affiliates, through no act or failure to act on the party of the Receiving Party or any of its Affiliates in violation of this Agreement; or
- **12.2.5** is independently discovered or developed by or on behalf of the Receiving Party or its Affiliates without the use of or reference to Confidential Information of the Disclosing Party or its Affiliates.
- **12.3 Authorized Disclosure**. The Receiving Party may disclose Confidential Information belonging to the Disclosing Party or its Affiliates only to the extent such disclosure is reasonably necessary in the following instances:
  - **12.3.1** filing, prosecuting, maintaining, enforcing or defending Patents as permitted by this Agreement;

- **12.3.2** as reasonably required in generating Regulatory Filings and filing for and obtaining Regulatory Approvals as permitted by this Agreement;
- **12.3.3** prosecuting or defending litigation or arbitration, including responding to a subpoena in a Third Party litigation or arbitration;
- **12.3.4** subject to Section 12.5, complying with Laws (including the rules and regulations of the U.S. Securities and Exchange Commission or any national securities exchange) and with judicial process, including as a result of any actions taken by a Party not in violation of this Agreement; and
- with respect to Confidential Information that is not a Fate Confidential Method or Janssen 12.3.5 Confidential Method, disclosure, solely on a "need to know basis", to Affiliates, potential or actual acquirers, merger partners, or assignees, Third Party collaborators (including Sublicensees), contractors or services providers regarding Collaboration Candidates or Licensed Products, investment bankers, investors, lenders, or other potential financial partners, consultants, agents and advisors, and the Receiving Party's directors, officers, employees, contractors and agents, each of whom prior to disclosure shall be bound by obligations of confidentiality and restrictions on use of such Confidential Information that are no less restrictive than the obligations in this ARTICLE 12; provided, however, that in the case of disclosures made to clinical trial sites, investigators, CROs or other Third Parties directly involved in the Research and Development of the Collaboration Candidates or Licensed Products, the duration for the obligations of confidentiality and non-use provided in the Receiving Party's agreement with such clinical trial sites, investigators, CROs or other Third Parties may be less than the duration for the obligations of confidentiality and non-use in this Agreement so long as such agreement specifies a duration for the obligations of confidentiality and restrictions on use of Confidential Information that are consistent with such obligations and restrictions agreed to by the Receiving Party in the ordinary course of business under similar circumstances; and provided further, that in each of the above situations, the Receiving Party shall remain responsible for any failure by any Person who receives Confidential Information pursuant to this Section 12.3.5 to treat such Confidential Information as required under this ARTICLE 12.

If and whenever any Confidential Information is disclosed in accordance with this Section 12.3, such disclosure shall not cause any such information to cease to be Confidential Information except to the extent that the exceptions set forth in Section 12.2.1 or Section 12.2.4 apply to such Confidential Information. Where reasonably possible and legally permitted and subject to Section 12.5, the Receiving Party shall notify the Disclosing Party of the Receiving Party's intent to make a disclosure pursuant to Section 12.3.3 or 12.3.4, sufficiently prior to making such disclosure so as to allow the Disclosing Party adequate time to take whatever action it may deem appropriate to protect the confidentiality of the Confidential Information. In this case, the Receiving Party must reasonably cooperate with the Disclosing Party's efforts, including by using not less than the same efforts to secure confidential treatment of such information as it would to protect its own confidential information from disclosure (but not less than reasonable efforts). In the event a Party intends to make a disclosure of the other Party's or its Affiliate's Confidential Information pursuant to Section 12.3.5 to a Third Party, it will give to the other Party reasonable advance notice of and information regarding the nature of such disclosure.

- **12.4 Terms of this Agreement**. The Parties acknowledge that this Agreement and all of the respective terms of this Agreement shall be treated as Confidential Information of both Parties.
- 12.5 Securities Filings. In the event either Party proposes to file with the Securities and Exchange Commission or the securities regulators of any state or other jurisdiction a registration statement or any other disclosure document which, in the reasonable opinion of such Party's counsel or independent financial auditor, requires disclosure of the terms and conditions of this Agreement or other information relating to this Agreement or the transactions contemplated hereby under the Securities Act of 1933, as amended, the Securities Exchange Act of 1934, as amended, or any other applicable securities Law, such Party shall notify the other Party of such intention and opinion and shall provide such other Party with a copy of relevant portions of the proposed filing [\*\*\*] Business Days (or such shorter time as practicable) prior to such filing, including any exhibits thereto relating to the terms and conditions of this Agreement. The Party making such filing shall seek confidential treatment of the terms and conditions of this Agreement or any portion thereof that such other Party reasonably requests be kept confidential, and shall only disclose Confidential Information that it is advised by its counsel is legally required to be disclosed or by its independent financial auditor is required to be disclosed under applicable securities Law. No such notice is required under this Section 12.5 if the description of or reference to this Agreement included in the proposed filing has been included in any previous filing made in accordance with this Section 12.5 or otherwise approved for public disclosure by the other Party in writing.
- **12.6 Relationship to Confidentiality Agreement**. This Agreement supersedes the Prior CDA, *provided* that all "Confidential Information" disclosed or received by the Parties thereunder shall be deemed "Confidential Information" hereunder and shall be subject to the terms and conditions of this Agreement.
- **12.7 Equitable Relief.** Given the nature of the Confidential Information and the competitive damage that may result to a Party upon unauthorized disclosure, use or transfer of its Confidential Information to any Third Party, the Parties agree that monetary damages may not be a sufficient remedy for any breach of this ARTICLE 12. In addition to all other remedies, a Party shall be entitled to seek specific performance and injunctive and other equitable relief as a remedy for any breach or threatened breach of this ARTICLE 12.

## 12.8 Research Program Information and Scientific Publications.

**12.8.1 Research Program Information**. The Parties acknowledge and agree that the Research Program Information shall be deemed to be Confidential Information of both Parties for which each Party will be deemed a Receiving Party unless and until Janssen exercises the Commercial Option with respect to a Collaboration Candidate. If Janssen exercises the Commercial Option with respect to a Collaboration Candidate, [\*\*\*], *provided* that Janssen and Fate may continue to use such Research Program Information solely as permitted under Section 12.1(c) and Section 5.1. "**Research Program Information**" means: [\*\*\*]

### 12.8.2 Publication.

- (a) Either Party may publish or present results of any Clinical Trial conducted by such Party relating to a Licensed Product in journals or at conferences, subject to the prior review and comment by the other Party as set forth in Section 12.8.2(b); *provided*, *however*, that Janssen shall not have the right to make any such publication or presentation with respect to a Collaboration Candidate prior to exercise of the Commercial Option with respect thereto. The Party who conducted a Clinical Trial shall be responsible for registering such Clinical Trial in the appropriate clinical study registry and reporting Clinical Trial results as may be required under applicable Law.
- **(b)** The publishing Party shall provide the non-publishing Party with the opportunity to review any such proposed abstract, manuscript or presentation by delivering a copy thereof to the non-publishing Party no less than [\*\*\*] days ([\*\*\*] days with respect to abstracts) before its intended submission for publication or presentation. The non-publishing Party shall have [\*\*\*] days ([\*\*\*] days for abstracts) of its receipt of any such abstract, manuscript or presentation to comment, and the publishing Party shall consider in good faith such non-publishing Party's comments in such abstract, manuscript or presentation. In the event the non-publishing Party objects to the disclosure in writing within the applicable review period, the publishing Party agrees to delete from the proposed disclosure any of the non-publishing Party's Confidential Information upon the request of the non-publishing Party. In the event of concern over patent protection, the publishing Party shall not submit such publication or make such presentation containing such information until the non-publishing Party is given a reasonable period of time, and in no event less than [\*\*\*] days, to seek patent protection for any material in such publication or presentation which it believes is patentable, unless the publishing Party reasonably determines that publication of such information is required by applicable Law.

## 12.9 Publicity.

- **12.9.1** Upon execution of this Agreement, Fate may, but is not obligated to, issue the press release announcing the execution of this Agreement in the form as set forth in **Exhibit 12.9.1** at a mutually agreed time.
- 12.9.2 Except as required to comply with applicable Law or as permitted by Sections 12.3, 12.5 or 12.9.1, if either Party intends to issue any press release or other public statement disclosing the transactions contemplated hereby, it shall give the other Party a reasonable opportunity to review and comment and shall consider any such comments in good faith. In addition, such Party shall not issue such press release or public statement without the prior written consent of the other Party (not to be unreasonably withheld, delayed, or conditioned). If a Party intends to issue such a press release or other public statement as required to comply with applicable Law, such Party will, except where impracticable or not legally permitted, give reasonable advance notice to the other Party of such disclosure. Notwithstanding the foregoing, once information relating to this Agreement has been publicly disclosed as permitted under this Agreement, neither Party shall be required to obtain the other Party's consent or provide notice of its further public disclosure, *provided* that such information remains accurate and not misleading in all material respects at the time of such further public disclosure.

#### **ARTICLE 13**

# REPRESENTATIONS, WARRANTIES, AND COVENANTS; DISCLAIMERS; LIMITATION OF LIABILITY

- **13.1 Mutual Representations and Warranties**. Each Party represents and warrants to the other Party as of the Effective Date that:
- **13.1.1** such Party is duly organized, validly existing and in good standing under the Laws of the jurisdiction of its incorporation and has full corporate power, ability and authority to enter into this Agreement and to carry out the provisions hereof;
- **13.1.2** execution of this Agreement and the performance by such Party of its obligations hereunder have been duly authorized;
- **13.1.3** this Agreement has been duly executed and delivered on behalf of such Party, the Person or Persons executing this Agreement on its behalf have been duly authorized to do so by all requisite corporate action, and this Agreement constitutes a legal, valid, binding obligation, enforceable against it in accordance with the terms hereof;
- **13.1.4** the execution, delivery and performance of this Agreement by such Party does not create a breach or default under any other agreement to which it is a party or by which it is bound, nor violate any Law or regulation of any court, governmental body or administrative or other agency having jurisdiction over such Party;
- 13.1.5 no government authorization, consent, approval, license, exemption of or filing or registration with any court or governmental department, commission, board, bureau, agency or instrumentality, domestic or foreign, under any Laws currently in effect, is necessary for, or in connection with, the transaction contemplated by this Agreement or any other agreement or instrument executed in connection herewith, or for the performance by it of its obligations under this Agreement and such other agreements, and except for Regulatory Approvals including Commercialization Approvals obtained in accordance with this Agreement; and
- **13.1.6** all of its directors, employees and officers have executed agreements requiring assignment to such Party of all Inventions, whether or not patentable, made during the course of and as a result of their association with such Party and obligating each such directors, employee and officer to maintain as confidential the Confidential Information of such Party.
- **13.2 Additional Representations and Warranties of Fate**. Fate hereby represents and warrants to Janssen, as of the Effective Date, that:
- 13.2.1 Fate (or its Affiliates) Controls the Fate Research Patents set forth on **Exhibit 13.2.1** and Fate Research Know-How and has the right to grant the licenses to Janssen as set forth in Section 5.1, and the Fate Research Patents set forth on **Exhibit 13.2.1** include all of the Patents owned by or licensed to Fate or its Affiliates as of the Effective Date that are reasonably necessary for the Parties to conduct their respective activities under the Research Plan as in existence as of the Effective Date; with respect to the Fate Research Patents, **Exhibit 13.2.1** accurately lists each patent family and countries of filing, including the owners of each item and, if the item is licensed to Fate or its Affiliates, the agreement pursuant to which such license was granted;
  - **13.2.2** to the knowledge of Fate as of the Effective Date[\*\*\*];

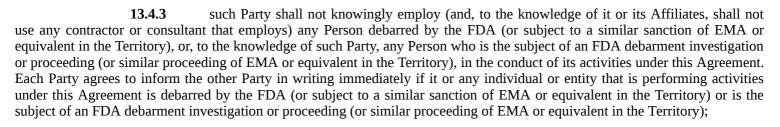
13.2.3	[***];	
13.2.4	[***]	

- **13.2.5** all tangible information and data provided by or on behalf of Fate or its Affiliates to Janssen on or before the Effective Date [\*\*\*];
- **13.2.6** Fate and its Affiliates have taken commercially reasonable steps to protect, preserve and maintain the confidentiality of all confidential or non-public information included in Fate Research Know-How, including by [\*\*\*];
- 13.2.7 Fate has provided Janssen with a true and complete copy of each of the Existing Agreements (except for redactions of terms not material to Janssen's rights thereunder), and each Existing Agreement is in full force and effect. No written notice of default or termination has been received or given, or to Fate's knowledge, threatened, under any Existing Agreement, and to the knowledge of Fate, there is no act or omission by Fate or its Affiliates, or by any counterparty to any Existing Agreement, that would provide a right to terminate any Existing Agreement. Neither Fate nor any of its Affiliates has waived any material right under any Existing Agreement;
- **13.2.8** Fate and its Affiliates have not, as of the Effective Date, granted any license to any Third Party, or entered into any agreement with any Third Party that would conflict or interfere with any of the rights or licenses granted to Janssen hereunder;

13.2.9	[***],
13.2.10	to the knowledge of Fate, [***];
13.2.11	to the knowledge of Fate, [***];
13.2.12	to the knowledge of Fate, [***];
13.2.13	neither Fate nor its Affiliates, nor, to the knowledge of Fate, [***]; and
13.2.14	Fate has made available to Janssen [***].

- **13.3 Additional Representations and Warranties of Janssen**. Janssen hereby represents and warrants to Fate, as of the Effective Date, that:
- **13.3.1** Janssen (or its Affiliates) Controls the Janssen Research Patents and has the right to grant the licenses to Fate as set forth in Section 5.2;
  - **13.3.2** to the knowledge of Janssen as of the Effective Date[\*\*\*];
  - 13.3.3 [\*\*\*];

- 13.3.4 to the knowledge of Janssen or its Affiliates, all inventors in Janssen Research Patents that are owned by Janssen are correctly identified in compliance with Law in the various jurisdictions, and all (i) inventors of the Janssen Research Patents owned jointly by Janssen that are employees of Janssen, in each case (i) and (ii) have agreed to assign to Janssen their entire rights, title and interest to and in inventions claimed in such Janssen Research Patents and any intellectual property thereto, and no other Person has any claim of ownership or inventorship whatsoever with respect to such Janssen Research Patents;
  - **13.3.5** to the knowledge of Janssen or its Affiliates[\*\*\*];
  - 13.3.6 [\*\*\*]
- 13.3.7 Janssen and its Affiliates have not received any written notice from or been investigated by, any court or governmental body or administrative or other agency having jurisdiction over activities of Janssen or its Affiliates, including Regulatory Authorities, claiming or suggesting that performance of its obligations hereunder or any other activities or business operation of Janssen or its Affiliates related to Antigen Binding Domains that Janssen intends to provide to Fate under the Research Programs for Janssen Antigen 1 or Janssen Antigen 2 have violated or may violate any Law, including if applicable GLP, GMP or GCP;
  - **13.3.8** to the knowledge of Janssen, [\*\*\*];
  - **13.3.9** neither Janssen nor its Affiliates nor, to the knowledge of Janssen, [\*\*\*]; and
- **13.3.10** Janssen and its Affiliates have not, as of the Effective Date, granted any license to any Third Party, or entered into any agreement with any Third Party that would conflict or interfere with any of the rights or licenses granted to Fate hereunder.
  - **Mutual Covenants.** Each Party hereby covenants to the other Party that during the Term:
- **13.4.1** all directors, officers, and employees of such Party or its Affiliates working under this Agreement shall be under the obligation to assign all right, title and interest in and to their inventions and discoveries, whether or not patentable, if any, to such Party as the sole owner thereof;
- 13.4.2 such Party shall perform its activities pursuant to this Agreement and obtain, generate, prepare, maintain and retain all data, regulatory documentation that is required to be obtained, generated, maintained or retained in compliance with GLP, GCP, GTP and GMP, in each case as applicable under the Laws and regulations of the country and the state and local government wherein such activities are conducted, as determined by such Party using reasonable discretion, and with respect to the consent eligibility, care, handling and use in Research, Development and Commercialization activities hereunder of any human or non-human animals sourced by or on behalf of such Party, shall at all times comply (and shall require compliance by any of its Third Party contractors) with all Laws, and also with the standards in the pharmaceutical industry for the research, development and commercialization of pharmaceutical products;



- 13.4.4 such Party shall not (a) enter into any agreement, instrument or understanding, oral or written, with any Third Party or (b) grant any license to any Third Party relating to any of the intellectual property rights it Controls, in each case (a) or (b) which would conflict or interfere with any of the rights or licenses granted to the other Party hereunder; and
- 13.4.5 such Party shall ensure that the Patents and Know-How licensed to the other Party hereunder will be free and clear of liens, charges or encumbrances other than (a) licenses granted to or by Third Parties that are not inconsistent with the rights and licenses granted to the other Party hereunder or (b) any other liens, charges or encumbrances that do not affect the other Party's rights hereunder.

## 13.5 Compliance with Anti-Corruption Laws.

- 13.5.1 Notwithstanding anything to the contrary in the Agreement, each Party hereby agrees that:
- (a) it shall not, in the performance of this Agreement, perform any actions that are prohibited by local and other anti-corruption laws (including the provisions of the U.S. Foreign Corrupt Practices Act, collectively "Anti-Corruption Laws") that may be applicable to one or both Parties to this Agreement;
- (b) it shall not, in the performance of this Agreement, directly or indirectly, make any payment, or offer or transfer anything of value, or agree or promise to make any payment or offer or transfer anything of value, to a government official or government employee, to any political party or any candidate for political office or to any other Third Party related to the transaction with the purpose of influencing decisions related to either Party or its business in a manner that would violate Anti-Corruption Laws;

- (c) Fate shall designate an individual within its organization [\*\*\*] as well as applicable rules on interactions with health care professionals, as mutually agreed to by the Parties. Such designated individual shall [\*\*\*] who perform any activities under this Agreement and interact with government officials or health care professionals in the normal course of their responsibilities. Upon the Parties' mutual agreement, [\*\*\*]. Fate and Janssen shall each use reasonable efforts to provide such training or training materials to any contractors or subcontractors of such Party engaged to perform activities under this Agreement where such contracted or subcontracted activities include responsibility for, directly or indirectly, interacting with Public Officials. Fate may fulfill its obligation under the preceding sentence by requesting appropriate materials from Janssen and forwarding such materials, if any, received from Janssen to the applicable contractor or subcontractor. In the event that Fate is not able to obtain a contractor or subcontractor's agreement to receive such training or materials, Fate will use reasonable efforts [\*\*\*] and materials for any such obligations;
- (d) it shall, on an annual basis upon request by the other Party, verify in writing that to the best of such Party's knowledge, there have been no violations of Anti-Corruption Laws by such Party or persons employed by or subcontractors used by such Party in the performance of the Agreement, or will provide details of any exception to the foregoing; and
- (e) it shall maintain records (financial and otherwise) and supporting documentation related to the subject matter of the Agreement in order to document or verify compliance with the provisions of this Section, and upon request of the other Party, up to once per year and upon reasonable advance notice, shall provide a Third Party auditor mutually acceptable to the Parties with access to such records for purposes of verifying compliance with the provisions of this Section. Acceptance of a proposed Third Party auditor may not be unreasonably withheld by either Party. It is expressly agreed that the costs related to the Third Party auditor will be fully paid by the Party requesting the audit, and that any auditing activities may not unduly interfere with the normal business operations of the Party subject to such auditing activities. The audited Party may require the Third Party auditor to enter into a reasonable confidentiality agreement in connection with such an audit.
- **13.5.2** Each Party hereby represents and warrants to the other Party that, to its knowledge as of the Effective Date, since [\*\*\*], neither such Party nor any of its subsidiaries nor any of their Affiliates, directors, officers, employees, distributors, agents, representatives, sales intermediaries or other Third Parties acting on behalf of such Party or any of its subsidiaries or any of their Affiliates:
  - (a) has taken any action in violation of any applicable Anti-Corruption Law; or

gift of anything of value, directly or indirectly, to any Public Official (as defined in Section 13.5.4 below), for the purposes of:		
capacity;	(i)	influencing any act or decision of any Public Official in his official
his lawful duty;	(ii)	inducing such Public Official to do or omit to do any act in violation of
	(iii)	securing any improper advantage; or
(iv) inducing such Public Official to use his or her influence government, governmental entity, or commercial enterprise owned or controlled by any government (includity owned or controlled veterinary or medical facilities) in obtaining or retaining any business whatsoever.		
	_	

has corruptly offered, paid, given, promised to pay or give, or authorized the payment or

13.5.3 Each Party hereby represents and warrants to the other Party that, as of the Effective Date, none of the officers, directors or employees of such Party or of any of its subsidiaries or agents acting on behalf of such Party or any of its subsidiaries, in each case that are employed or reside outside the United States, are themselves Public Officials.

# **13.5.4** For purposes of this Agreement, "**Public Official**" means:

(b)

- (a) any officer, employee or representative of any regional, federal, state, provincial, county or municipal government or government department, agency or other division;
- **(b)** any officer, employee or representative of any commercial enterprise that is owned or controlled by a government, including any state-owned or controlled veterinary or medical facility;
- **(c)** any officer, employee or representative of any public international organization, such as the African Union, the International Monetary Fund, the United Nations or the World Bank; and
- **(d)** any person acting in an official capacity for any government or government entity, enterprise or organization identified above.

#### 13.6 DISCLAIMERS.

- 13.6.1 EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, FATE MAKES NO REPRESENTATIONS OR WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING ANY EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, WITH RESPECT TO ANY FATE CONFIDENTIAL INFORMATION OR ANY LICENSE GRANTED BY FATE UNDER ITS INTELLECTUAL PROPERTY RIGHTS HEREUNDER, OR WITH RESPECT TO ANY ANTIGEN BINDING DOMAIN, COLLABORATION CANDIDATE. LICENSED COLLABORATION CANDIDATE, OR LICENSED PRODUCT.
- 13.6.2 EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, JANSSEN MAKES NO REPRESENTATIONS OR WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING ANY EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, WITH RESPECT TO ANY JANSSEN CONFIDENTIAL INFORMATION OR ANY LICENSE GRANTED BY JANSSEN UNDER ITS INTELLECTUAL PROPERTY RIGHTS HEREUNDER, OR WITH RESPECT TO ANY ANTIGEN BINDING DOMAIN, COLLABORATION CANDIDATE, LICENSED COLLABORATION CANDIDATE, OR LICENSED PRODUCT.
- 13.7 LIMITATION OF LIABILITY. EXCEPT FOR CLAIMS OF A THIRD PARTY THAT ARE SUBJECT TO INDEMNIFICATION UNDER ARTICLE 14, NEITHER PARTY SHALL BE LIABLE TO THE OTHER WITH RESPECT TO ANY SUBJECT MATTER OF THIS AGREEMENT, WHETHER UNDER ANY CONTRACT, NEGLIGENCE, STRICT LIABILITY OR OTHER LEGAL OR EQUITABLE THEORY, FOR ANY INCIDENTAL, INDIRECT, SPECIAL, EXEMPLARY, PUNITIVE, MULTIPLE, OR CONSEQUENTIAL DAMAGES, (INCLUDING LOST PROFITS, LOSS OF USE, DAMAGE TO GOODWILL, LOSS OF OPPORTUNITIES, OR LOSS OF BUSINESS).

### **ARTICLE 14**

### INDEMNITY AND INSURANCE

**14.1 Janssen Indemnity**. Janssen shall indemnify, defend and hold harmless Fate and its Affiliates, and their respective officers, directors, employees, agents, Sublicensees, and their respective successors, heirs and assigns and representatives (the "**Fate Indemnitees**"), from and against any and all claims, threatened claims, damages, losses, suits, proceedings, liabilities, costs (including reasonable legal expenses, reasonable costs of litigation and reasonable attorney's fees), or judgments, whether for money or equitable relief, of any kind brought by a Third Party or Governmental Authority (collectively, "**Losses**"), to the extent arising out of or relating to: [\*\*\*]. For clarity, Losses shall not include any losses or damages sustained by any Fate Indemnitee as a result of the actions described in clauses (a), (b) or (c) of the immediately preceding sentence, except to the extent that such losses or damages are paid or incurred by a Fate Indemnitee to a Third Party or Governmental Authority as a result of a claim or action of a Third Party or Governmental Authority.

- **14.2 Fate Indemnity**. Fate shall indemnify, defend and hold harmless Janssen and its Affiliates, and their respective officers, directors, employees, agents, Sublicensees, and their respective successors, heirs and assigns and representatives (the "**Janssen Indemnitees**"), from and against any and all Losses, to the extent arising out of or relating to: [\*\*\*]. For clarity, Losses shall not include any losses or damages sustained by any Janssen Indemnitee as a result of the actions described in clauses (a), (b) or (c) of the immediately preceding sentence, except to the extent that such losses or damages are paid or incurred by a Janssen Indemnitee to a Third Party or Governmental Authority as a result of a claim or action of a Third Party or Governmental Authority.
- 14.3 **Indemnification Procedure.** A claim to which indemnification applies under Section 14.1 or Section 14.2 shall be referred to herein as an "Indemnification Claim". If any Person or Persons (collectively, the "Indemnitee") intends to claim indemnification under this ARTICLE 14, the Indemnitee shall notify the other Party (the "Indemnitor") in writing promptly upon becoming aware of any claim that may be an Indemnification Claim (it being understood and agreed, however, that the failure by an Indemnitee to give such notice shall not relieve the Indemnitor of its indemnification obligation under this Agreement except and only to the extent that the Indemnitor is actually prejudiced as a result of such failure to give notice). Each claim notice shall describe in reasonable detail the basis for such claim (the "Claim Basis") and specify the amount or the estimated amount of Losses actually incurred or paid by the Indemnitee as a result of the Claim Basis, to the extent ascertainable. By delivering notice to the Indemnitee within [\*\*\*] days after delivery of notice described in the immediately preceding sentence, the Indemnitor may assume and control, with the sole power to direct, the defense of the Indemnification Claim at its own expense with counsel selected by the Indemnitor and reasonably acceptable to the Indemnitee. If the Indemnitor does not assume control of the defense of the Indemnification Claim as described in this Section 14.3, above, the Indemnitee shall control such defense at Indemnitor's expense (subject to Sections 14.1 and 14.2). The Party not controlling such defense may participate therein at its own expense. Neither the Indemnitor nor the Indemnitee shall admit fault on behalf of the other Party without the written consent of such other Party. The Indemnitee shall not settle or compromise an Indemnification Claim without the prior written consent of the Indemnitor, which shall not be unreasonably withheld, delayed or conditioned. The Indemnitor shall not settle or compromise an Indemnification Claim or consent to any judgment in respect thereof that does not include a complete and unconditional release of the Indemnitee from all liability with respect thereto or that imposes any liability or obligation on the Indemnitee for which the Indemnitee is not indemnified under this Agreement, without the prior written consent of the Indemnitee. The Party controlling the defense of an Indemnification Claim shall keep the other Party advised of the status of such Indemnification Claim and the defense thereof and shall reasonably consider recommendations made by the other Party with respect thereto. The other Party shall cooperate fully with the Party controlling such defense and shall make available all pertinent information under its control, which information shall be subject to ARTICLE 12, and cause its employees to be available in a deposition, hearing or trial.
- **14.4 Insurance**. Each Party shall acquire and maintain, at its own expense, insurance or self-insurance, as reasonably necessary to cover its own product liability and its obligations under this Agreement. Within [\*\*\*] days following written request from the other Party, each Party shall furnish to such other Party a certificate of insurance evidencing such coverage.

# ARTICLE 15 Term and Termination

- **15.1 Term; Expiration**. The term of this Agreement (the "**Term**") shall become effective as of the Effective Date and shall continue in full force and effect, unless earlier terminated pursuant to the rest of this ARTICLE 15, until:
- **15.1.1** on a Janssen Antigen-by-Janssen Antigen basis, the expiration of the last Commercial Option Term for a Collaboration Candidate in the Research Plan for such Janssen Antigen without Janssen's exercise of the Commercial Option for any Collaboration Candidate with respect to such Janssen Antigen;
- 15.1.2 if Janssen exercises a Commercial Option, on a Licensed Product-by-Licensed Product and country-by-country basis, (a) if such Licensed Product is not a Profit Share Product, on the date of expiration of the Royalty Term with respect to such Licensed Product in such country or (b) if such Licensed Product is a Profit Share Product, on the date of expiration of all payment obligations in such country under Section 6.4 of the Profit Share Product Exhibit (with respect to the U.S.) and under Section 6.5 of the Profit Share Product Exhibit (with respect to any other country);
- **15.1.3** if the Agreement expires with respect to all of the Janssen Antigens under Section 15.1.1, in its entirety upon the expiration of the Agreement with respect to the last Janssen Antigen;
- **15.1.4** if Janssen exercises a Commercial Option, on a Janssen Antigen-by-Janssen Antigen basis, upon the expiration of this Agreement with respect to all Licensed Products in all countries in the Territory under Section 15.1.2 with respect to such Janssen Antigen; or
- **15.1.5** if Janssen exercises a Commercial Option, in its entirety upon expiration of this Agreement with respect to all Licensed Products in all countries in the Territory under Section 15.1.2.

Upon the expiration of this Agreement pursuant to Section 15.1.2 on a Licensed Product-by-Licensed Product and country-by-country basis, the licenses granted by Fate to Janssen under Section 5.1.2 with respect to such Licensed Product and country shall become fully paid-up, non-exclusive, irrevocable, royalty-free and perpetual; *provided*, *however*, that such Licensed Product in such country shall still be included in the calculation of Annual Net Sales in Section 10.5.

### 15.2 Termination for Material Breach.

- 15.2.1 Either Party (the "Non-breaching Party") may terminate this Agreement in its entirety in the event of a material breach of this Agreement by the other Party (the "Breaching Party"), by providing [\*\*\*] days' prior written notice to the Breaching Party (the "Cure Period"). Such notice shall reasonably describe the alleged material breach in sufficient detail to put the Breaching Party on notice and clearly state the Non-breaching Party's intent to terminate this Agreement if the alleged breach is not cured within the Cure Period. Notwithstanding the foregoing: (i) the Cure Period in connection with a material breach of a payment obligation under ARTICLE 10 of this Agreement or ARTICLE VI of the Profit Share Product Exhibit shall be [\*\*\*] days; and (ii) if the alleged material breach (other than a payment breach), by its nature, is curable, but is not reasonably curable within the Cure Period, then such Cure Period shall be extended if the Breaching Party provides a written plan for curing such breach to the Non-breaching Party and uses [\*\*\*] Efforts to cure such breach in accordance with such written plan, provided that no such extension shall exceed [\*\*\*] days without the consent of the Non-breaching Party.
- 15.2.2 If the Breaching Party disputes in good faith the existence or materiality of a breach specified in a notice provided by the other Party in accordance with Section 15.2.1, and the Breaching Party provides the other Party notice of such dispute within the Cure Period, then the non-breaching Party shall not have the right to terminate this Agreement under Section 15.2.1 unless and until (i) the dispute resolution process in ARTICLE 16 has finally determined that the Breaching Party has materially breached this Agreement and (ii) the Breaching Party fails to cure such material breach within ninety [\*\*\*] (or [\*\*\*] days in the case of the breach of a payment obligation) following such final determination. It is understood and agreed that, during the pendency of such dispute, all of the terms and conditions of this Agreement shall remain in effect and the Parties shall continue to perform all of their respective obligations hereunder.
- **15.3 Janssen Unilateral Termination Rights**. Janssen may terminate this Agreement at any time on a Janssen Antigen-by-Janssen Antigen basis, which termination shall include all Collaboration Candidates, Rejected Candidates, Discontinued Collaboration Candidates, Licensed Collaboration Candidates and Licensed Products, and all of their Equivalents, with respect to such Janssen Antigen, or in its entirety, upon [\*\*\*] days written notice to Fate; *provided* that such termination will not take effect until on or after the [\*\*\*] anniversary of the Effective Date.
- **Termination for** [\*\*\*]. Fate shall have the right to terminate this Agreement with respect to a particular Janssen Antigen upon written notice to Janssen within [\*\*\*] after the applicable date if [\*\*\*].

### **15.5** Termination for Insolvency.

15.5.1 Either Party may terminate this Agreement if, at any time, the other Party files in any court or agency pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of the Party or of substantially all of its assets, or if the other Party is served with an involuntary petition against it, filed in any insolvency proceeding, and such other Party consents to the involuntary bankruptcy or such petition is not dismissed within [\*\*\*] days after the filing thereof, or if the other Party shall propose or be a party to any dissolution or liquidation, or if the other Party shall make an assignment of substantially all of its assets for the benefit of creditors (each, an "Insolvency Event").

All rights and licenses now or hereafter granted by Fate to Janssen under or pursuant to this 15.5.2 Agreement, including, for the avoidance of doubt, the licenses granted to Janssen pursuant to Section 5.1 and 5.4, are, for all purposes of Section 365(n) of Title 11 of the United States Code, as amended (such Title 11, the "Bankruptcy Code"), licenses of rights to "intellectual property" as defined in the Bankruptcy Code. Upon the occurrence of any Insolvency Event with respect to Fate, Fate agrees that Janssen, as licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code. Without limiting the generality of the foregoing, Fate and Janssen intend and agree that any sale of Fate's assets under Section 363 of the Bankruptcy Code shall be subject to Janssen's rights under Section 365(n), that Janssen 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 Janssen's rights under this Agreement and Section 365(n) without the express, contemporaneous consent of Janssen. Further, each Party agrees and acknowledges that no payments by Janssen to Fate hereunder, other than royalty payments pursuant to Section 10.6 of this Agreement or Section 6.5 of Profit Share Product Exhibit, U.S. Pre-Tax Profits and Losses payments pursuant to Section 6.4 of the Profit Share Product Exhibit and payments for Sales Milestone Events pursuant to Section 10.5 of this Agreement or pursuant to Section 6.2 of the Profit Share Product Exhibit, shall constitute royalties within the meaning of Section 365(n) of the Bankruptcy Code and relate to licenses of intellectual property hereunder. Fate shall, 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. Fate and Janssen acknowledge and agree that "embodiments" of intellectual property within the meaning of Section 365(n) include the Master iPSC Bank, any CD34 Compositions, laboratory notebooks, cell lines, product samples and inventory, research studies and data, Regulatory Filings and Regulatory Approvals. If (i) a case under the Bankruptcy Code is commenced by or against Fate, (ii) this Agreement is rejected as provided in the Bankruptcy Code, and (iii) Janssen elects to retain its rights hereunder as provided in Section 365(n) of the Bankruptcy Code, Fate (in any capacity, including debtor-in-possession) and its successors and assigns (including a trustee) shall:

(a) provide to Janssen all such intellectual property (including all emboding	nents thereof) held
by Fate and such successors and assigns, or otherwise available to them, immediately upon Janssen's written r	equest. Whenever
Fate or any of its successors or assigns provides to Janssen any of the intellectual property licensed l	hereunder (or any
embodiment thereof) pursuant to this Section 15.5.2, Janssen shall have the right to perform Fate's obligation	ns hereunder with
respect to such intellectual property, but neither such provision nor such performance by Janssen shall release	Fate from liability
resulting from rejection of the license or the failure to perform such obligations; and; and	

**(b)** not interfere with Janssen'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 Bankruptcy Code.

15.5.3 All rights, powers and remedies of Janssen provided herein are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in equity (including the Bankruptcy Code) in the event of the commencement of a case under the Bankruptcy Code with respect to Fate. The Parties agree that they intend the following rights to extend to the maximum extent permitted by law, and to be enforceable under Bankruptcy Code Section 365(n):

(a) the right of access to any intellectual property (including all embodiments thereof) of Fate, or any Third Party with whom Fate contracts to perform an obligation of Fate under this Agreement, and, in the case of the Third Party, which is necessary for the manufacture, use, sale, import or export of Collaboration Candidates or Licensed Products; and

**(b)** the right to contract directly with any Third Party to complete the contracted work.

15.6	Termination for [***].			
	15.6.1	[***]		
	15.6.2	[***]		
	15.6.3	[***]		
	15.6.4	[***]		

## **15.7** Consequences of Termination.

- **15.7.1** In the event of termination of the Agreement by either Party pursuant to Section 15.2, 15.3, 15.4, 15.5 or 15.6, then, upon the effective date of such termination:
- (a) all licenses and other rights granted to either Party pursuant to this Agreement shall terminate (save for those (i) expressly stated to survive termination of this Agreement pursuant to Section 15.8, or (ii) to the extent necessary to enable either Party to perform any of its obligations that survive termination);
- (b) Janssen shall wind down any Development and Commercialization activities and any Manufacturing activities, as quickly as reasonably practicable, subject to compliance with ethical and legal requirements, and the Parties shall continue to be responsible for or share, as applicable, the costs of any such activities in accordance with the terms of this Agreement until such wind down is complete; *provided*, *however*, if Janssen terminates this Agreement pursuant to Section 15.3, or if Fate terminates this Agreement pursuant to Section 15.2 or 15.5, after the Opt-In Exercise Date for a Profit Share Product, then the provisions of Section 9.1 of the Profit Share Product Exhibit shall apply with respect to such Profit Share Product;
- (c) neither Party shall Develop, Manufacture or Commercialize any Collaboration Candidates, Rejected Candidates, Discontinued Collaboration Candidates, Licensed Collaboration Candidates, or Licensed Products, or any of their Equivalents, and Fate shall have no further right to use the Janssen Antigen Binding Domains provided to Fate by Janssen, except in each case as provided with respect to Reverted Profit Share Products pursuant to Section 9.1 of the Profit Share Product Exhibit;
- (d) each Party shall use [\*\*\*] Efforts to return or destroy, at the Disclosing Party's election, all Confidential Information of the other Party (*provided*, *however*, that the Receiving Party may keep one copy of such Confidential Information subject to an ongoing obligation of confidentiality for archival purposes only), except for any Confidential Information to which the Receiving Party has a continuing right of use (which, for clarity, shall not include any Fate Confidential Methods). This obligation to return or destroy Confidential Information does not extend to automatically generated computer back-up or archival copies generated in the ordinary course of information system's procedures, *provided*, *however*, that except as expressly set out herein, the Receiving Party shall not access nor make any use of such copies;
- **(e)** Subject to Fate's rights under the Profit Share Product Exhibit, Janssen shall return to Fate or destroy (and certify such destruction in writing) all Master iPSC Banks, all working cell banks, and CD34 Compositions. Janssen shall assign, and hereby does assign, to Fate title to the Master iPSC Banks, all working cell banks, and CD34 Compositions therefor; and

- All of the foregoing effects of termination are in addition to the other rights and remedies that may be available to the Parties at law or in equity. If this Agreement is terminated with respect to one or more Janssen Antigens (including all Collaboration Candidates, Rejected Candidates, Discontinued Collaboration Candidates, Licensed Collaboration Candidates, Licensed Products, and all of their Equivalents with respect thereto) but not in its entirety, such effects will apply only to the terminated Research Program with respect to such Janssen Antigen (including all Collaboration Candidates, Rejected Candidates, Discontinued Collaboration Candidates, Licensed Collaboration Candidates, Licensed Products, and all of their Equivalents with respect thereto).
- **15.8 Survival**. Unless otherwise expressly provided herein, the following provisions shall survive termination or expiration of this Agreement in its entirety (including any other Sections, Articles or defined terms referred to in such provisions or necessary to give them effect), as well as any other provision which by its terms or by the context thereof, is intended to survive such termination:

Section 3.7.6

Section 3.10 (Materials)

Section 5.1.4(b)

Section 5.1.5 (Fate Affiliates)

Section 5.2.4 (Janssen Affiliates)

[\*\*\*]

Section 5.4 (Collaboration Intellectual Property)

Section 5.5.1 (Sublicenses to Affiliates)

Section 5.9.1 (No Implied Licenses; Retained Rights)

Sections 10.2 (Payments during Research Term) through 10.9 (Manner of Payment), to the extent necessary to determine or pay any amounts that were incurred, or that became due and payable, prior to the effective date of termination

Section 10.10 (Records)

Section 10.11 (Audits)

Section 10.12 (Taxes)

Section 11.1 (Inventions)

Section 11.2.3 (Joint Patents)

Sections 12.1 (Nondisclosure) through 12.7 (Equitable Relief), and Section 12.8.1 (Research Program Information), for the time period set forth in Section 12.1

Section 13.6 (Disclaimers)

Section 13.7 (Limitation of Liability)

ARTICLE 14 (Indemnity and Insurance)

Section 15.1 (Term; Expiration), last paragraph

Section 15.7 (Consequences of Termination)

Section 15.8 (Survival)

ARTICLE 16 (Dispute Resolution)

ARTICLE 17 (Miscellaneous), other than Section 17.12 (Competition Law Filings) and Section 17.14 (Effects of Fate Change of Control)

ARTICLE VI of <u>Exhibit 6.4</u> (Financial Provisions), to the extent necessary to determine or pay any amounts that were incurred, or that became due and payable, during the Profit Share Term prior to the effective date of termination

Section 6.3.2 of <u>Exhibit 6.4</u> (Development Costs Prior to Opt-In Exercise Date) ARTICLE VIII of <u>Exhibit 6.4</u> (Product Liability Claims) ARTICLE IX of <u>Exhibit 6.4</u> (Termination)

Termination or expiration of this Agreement shall not relieve the Parties of any liability or obligation which accrued hereunder prior to the effective date of such termination or expiration, nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity, subject to ARTICLE 16, with respect to any breach of this Agreement nor prejudice either Party's right to other remedies such Party may have at law or equity. Termination or expiration of this Agreement with respect to a portion of this Agreement (e.g., certain obligations, products or targets) shall not affect the Parties' respective rights and obligations in portions of this Agreement not so terminated.

# ARTICLE 16 DISPUTE RESOLUTION

- **16.1 Exclusive Dispute Resolution Mechanism**. The Parties agree that, except with respect to Committee Matters, which will be resolved in accordance with ARTICLE 2 or Section 2.6 of the Profit Share Product Exhibit, as applicable, the procedures set forth in this ARTICLE 16 shall be the exclusive mechanism for resolving any dispute, controversy, or claim between the Parties that may arise from time to time pursuant to, arising out of or in connection with this Agreement, including any Party's rights or obligations hereunder or any questions regarding the formation, existence, validity, enforceability, performance, interpretation, tort, breach or termination hereof (collectively, "**Disputes**") that cannot be resolved through good faith negotiation between the Parties.
- **Resolution by Executive Officers**. In the event of any Dispute, the Parties shall first attempt in good faith to resolve such Dispute by negotiation and consultation. In the event that such Dispute is not resolved through such negotiation within [\*\*\*] days after either Party's request, either Party may, by written notice to the other Party, refer the Dispute for attempted resolution by good faith negotiation between the Executive Officers within [\*\*\*] days after such notice is received. Except as set forth in Sections 16.4 and 16.5, if any Dispute is not resolved by the Executive Officers within the above [\*\*\*]-day period, each Party may, in its sole discretion, seek resolution of such Dispute in accordance with Section 16.3, and each Party hereby expressly waives its right to seek resolution of such Dispute in a court of competent jurisdiction.

### 16.3 Arbitration.

**16.3.1** With respect to any Disputes that are not resolved by the Executive Officers in accordance with Section 16.2, the Dispute shall be submitted by either Party for resolution in arbitration pursuant to the then current Commercial Arbitration Rules of the American Arbitration Association ("**AAA Rules**"), except where they conflict with this Section 16.3, in which case this Section 16.3 shall control.

- 16.3.2 A panel consisting of three (3) arbitrators, two (2) of whom are to be nominated by the Parties without knowing which Party nominated each of them, shall conduct the arbitration in accordance with the AAA Rules. Each Party shall nominate one (1) arbitrator and propose that potential arbitrator to the other Party. The other Party may object to the nomination on grounds of bias, lack of subject matter experience, or any other legitimate grounds. AAA will be the final decision maker if there is a dispute over the objection. Once each Party has identified an acceptable potential arbitrator, AAA will approach each potential arbitrator to determine whether he or she is willing and able to serve, without informing such potential arbitrator which Party nominated him or her. Once the Party-nominated arbitrators are established, the two (2) Party-nominated arbitrators shall nominate a third arbitrator, who shall act as chairperson. Each of the three arbitrators shall be a lawyer with at least [\*\*\*] years' experience with a law firm or corporate law department of over 25 lawyers or who was a judge of a court of general jurisdiction. Each arbitrator shall be impartial and independent of the Parties and shall abide by the *Code of Ethics for Arbitrators in Commercial Disputes*.
- **16.3.3** The seat, or legal place, of arbitration shall be New York, New York, and the language used in any such proceeding shall be English.
- 16.3.4 In such arbitration the governing law to be applied is as described in Section 17.7. It is the intent of the Parties to enable a reasonable and practicable amount of discovery in any proceeding. At the request of a Party, the arbitral tribunal shall have the discretion to order the disclosure of specified documents by the Parties. Such a request shall identify the document(s) with a reasonable degree of specificity and establish the relevance of the document(s) to the arbitration. The Parties agree that this Agreement evidences a transaction involving interstate commerce. Notwithstanding Section 17.7 with respect to applicable substantive law, any arbitration conducted pursuant to the terms of this Agreement shall be governed by the Federal Arbitration Act (9 U.S.C. §§ 1 et. seq.).
- **16.3.5** The Parties acknowledge that they desire for any arbitration to be conducted in an efficient, speedy and economical manner. The Parties shall use good faith efforts to complete arbitration under this Section 16.3 within [\*\*\*] following the appointment of the tribunal. In order to effectuate this desire, the arbitrators shall establish procedures reasonably directed to facilitating such goals and completing such arbitration within such [\*\*\*] period.
- **16.3.6** Except as otherwise specifically limited in this Agreement, the arbitral tribunal shall have the power to grant any remedy or relief that it deems appropriate, whether provisional or final, including but not limited to conservatory relief and injunctive relief.
- 16.3.7 The existence and content of the arbitral proceedings and any rulings or awards shall be kept confidential by the Parties and members of the arbitral tribunal except (i) to the extent that disclosure may be required of a Party to fulfill a legal duty, protect or pursue a legal right, or enforce or challenge an award in bona fide legal proceedings before a state court or other judicial authority, (ii) with the consent of the Parties, (iii) where needed for the preparation or presentation of a claim or defense in this arbitration, (iv) where such information is already in the public domain other than as a result of a breach of this Section 16.3.7, or (v) by order of the arbitral tribunal upon application of a Party.

- **16.3.8** The arbitration award shall be final and binding on the Parties, and the Parties undertake to carry out any award without delay. Judgment on the award may be entered in any court of competent jurisdiction.
- **16.3.9** Each Party shall bear its own costs and attorney's fees, and the Parties shall equally bear the fees, costs, and expenses of the arbitrators and the arbitration proceedings, including costs and expenses of translators for the arbitration proceedings; *provided*, *however*, that the arbitrators may exercise discretion to award arbitration costs and translation costs, excluding attorney's fees, to the prevailing Party.
- **16.4 Preliminary Injunctions**. Notwithstanding anything in this Agreement to the contrary, a Party may seek interim or conservatory measures, including a temporary restraining order or a preliminary injunction, from any court of competent jurisdiction in order to prevent immediate and irreparable injury, loss, or damage on a provisional basis, pending the decision of the arbitrator(s) on the ultimate merits of any Dispute. Any such request shall not be deemed incompatible with, or a waiver of, this agreement to arbitrate.
- **16.5 Patent Disputes**. Notwithstanding anything in this Agreement to the contrary, any and all issues regarding the scope, construction, validity, and enforceability of any patent in a country within the Territory shall be determined in a court of competent jurisdiction under the applicable patent laws of such country.
  - 16.6 No Trial by Jury. EACH PARTY HERETO WAIVES ITS RIGHT TO TRIAL OF ANY ISSUE BY JURY.

## ARTICLE 17 MISCELLANEOUS

- **17.1 Severability**. If any one or more of the provisions of this Agreement is held to be invalid, illegal or unenforceable, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good faith effort to replace any invalid, illegal or unenforceable provision with a valid, legal and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.
- **Notices**. Any notice required or permitted to be given by this Agreement shall be in writing and in English and shall be **(a)** delivered by hand or overnight courier with tracking capabilities or **(b)** mailed postage prepaid by first class, registered or certified mail addressed as set forth below unless changed by notice so given:

If to Janssen:
[***]
[***]
[***]

If to Fate:

Fate Therapeutics, Inc. 3535 General Atomics Court Suite 200 San Diego, California 92121 Attention: Chief Executive Officer

and

Fate Therapeutics, Inc. 3535 General Atomics Court Suite 200 San Diego, California 92121 Attention: Office of the General Counsel

Any such notice shall be deemed given (i) on the date received if delivered in accordance with Section 17.2(a), or (ii) [\*\*\*] Business Days after mailing if mailed in accordance with Section 17.2(b). 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 Party's notices in accordance with this Section 17.2. It is understood and agreed that this Section 17.2 does not intend to govern day-to-day business communications necessary between the Parties in performing their duties under the terms hereof.

17.3 **Force Majeure**. Neither Party shall be liable for delay or failure in the performance of any of its obligations hereunder (other than the payment of money) if such delay or failure is due to causes beyond its reasonable control, including, acts of God, fires, typhoon, floods, earthquakes, tsunami, embargoes, acts of war (whether war be declared or not), terrorism, strikes, lockouts, pandemics or other civil unrest, or omissions or delays in acting by any governmental authority ("**Force Majeure**"); *provided*, *however*, that the affected Party promptly notifies the other Party and further provided that the affected Party shall use its [\*\*\*] Efforts to avoid or remove such causes of non-performance and to mitigate the effect of such occurrence, and shall continue performance with the commercially reasonable dispatch whenever such causes are removed. When such circumstances arise, the Parties shall 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.

#### 17.4 Assignment.

17.4.1 Neither this Agreement nor any right or obligation of a Party hereunder may be assigned or transferred by either Party, in whole or in part, without the consent of the other Party, which shall not be unreasonably withheld, delayed or conditioned. Notwithstanding the foregoing, either Party may, without the consent of the other Party, assign or transfer all of its rights and obligations hereunder to: (a) an Affiliate, as long as the assignee remains an Affiliate of the assigning Party, provided that the assigning Party shall remain responsible for the performance of, and primarily liable under, this Agreement notwithstanding such assignment; or (b) a Third Party that acquires all or substantially all of the business or consolidated assets of such Party (whether by merger, reorganization, acquisition, sale or otherwise); provided, however, that (a) such assignment or transfer includes all rights and obligations under this Agreement, and (b) such Acquirer or Affiliate shall have agreed in writing, as of the date of such assignment or transfer, to be bound by the terms of this Agreement, and to assume performance of rights or obligations hereof.

- 17.4.2 Subject to Section 17.4.1, this Agreement shall inure to the benefit of and be binding on the Parties' successors and assigns. Any assignment or transfer in violation of the foregoing shall be null and void and wholly invalid, such assignees and transferees in any such assignment or transfer shall acquire no rights whatsoever, and the non-assigning or non-transferring Party shall not be required to recognize such assignment or transfer. In the event that a Party assigns or otherwise transfers this Agreement to an Affiliate of such Party, such Party hereby agrees to be jointly and severally liable with any such Affiliates for the actions of such Affiliates and for any and all amounts that become due and payable hereunder to the other Party.
- 17.4.3 Notwithstanding anything to the contrary in this Agreement, Fate shall have the right to assign its rights to receive payments pursuant to ARTICLE 10, in whole or in part, to a Third Party in connection with the monetization of Fate's revenue stream under ARTICLE 10 only with Janssen's prior written consent, which shall not be unreasonably withheld, conditioned or delayed.
- **17.5 Further Assurances**. At any time or from time-to-time on and after the Effective Date, either Party shall at the request of the other Party (a) deliver to the requesting Party such records, data or other documents required to be delivered under the provisions of this Agreement, and (b) execute, and deliver or cause to be delivered, all such consents, documents or further instruments of assignment, transfer or license consistent with the provisions of this Agreement.
- **17.6 Waivers.** The failure or delay of any Party to assert a right hereunder or to insist on the performance of any obligation hereunder shall not be deemed to be a waiver of that right or such obligation. Waiver of any breach of any provision hereof shall not be deemed to be a waiver of any other breach of such provision or any other provision on such occasion or any succeeding occasion. No waiver, modification, or release by either Party of any condition or term in any one or more instances shall be construed as a continuing waiver of such condition or term or of another condition or term. In any event no waiver shall be effective for any purpose hereunder unless such waiver is in writing and signed by a duly authorized officer of the Party granting such waiver.
- **17.7 Governing Law**. This Agreement shall be governed by, enforced, and shall be construed in accordance with the Laws of the State of New York without regard to any conflicts of law provision that would result in the application of the Laws of any other country or state. The Parties expressly agree that the United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Agreement.
- 17.8 Relationship of the Parties. Each Party is an independent contractor under this Agreement. Nothing contained herein is intended or is to be construed so as to constitute Fate and Janssen as partners, agents or joint venturers. Neither Party shall have any express or implied right or authority to assume or create any obligations on behalf of or in the name of the other Party or to bind the other Party to any contract, agreement or undertaking with any Third Party. Neither Party (nor its successor, assignee, transferee or Affiliate) shall treat or report the relationship between the Parties arising under this Agreement as a partnership for United States tax purposes without the prior written consent of the other Party, unless required by a final "determination" as defined in Section 1313 of the United States Internal Revenue Code of 1986, as amended.

- 17.9 Third Party Beneficiary. Except as expressly set forth herein, this Agreement is for the sole benefit of the Parties hereto and their successors and permitted assigns, and there are no express or implied third party beneficiaries hereunder except for Indemnitees specified in ARTICLE 14. Nothing in this Agreement shall be construed as giving any Person, other than the Parties and Indemnitees hereto and their successors and permitted assigns, any right, remedy or claim under or in respect of this Agreement or any provision hereof.
- **17.10 Entire Agreement; Amendment; Exhibits.** This Agreement and the attached exhibits constitute the entire agreement between the Parties as to the subject matter of this Agreement, and supersede and merge all prior and contemporaneous negotiations, representations, agreements and understandings regarding the same, including the Prior CDA, subject to Section 12.6. No subsequent alteration, amendment, change or addition to this Agreement shall be valid or binding upon the Parties unless in writing and signed by the respective duly authorized officers of each of the Parties. All Exhibits and Schedules are incorporated herein by this reference.

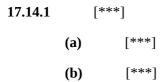
#### 17.11 Interpretation; Headings.

- 17.11.1 Each of the Parties acknowledges and agrees that this Agreement has been diligently reviewed by and negotiated by and between them, that in such negotiations each of them has been represented by competent counsel and that the final agreement contained herein, including the language whereby it has been expressed, represents the joint efforts of the Parties hereto and their counsel. Accordingly, in interpreting this Agreement or any provision hereof, no presumption shall apply against any Party as being responsible for the wording or drafting of this Agreement or any such provision, and ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision.
- 17.11.2 Unless the context requires otherwise, (a) any definition of or reference to any agreement, instrument or other document herein shall 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 or therein), (b) any reference to any Laws herein shall be construed as referring to such Laws as from time to time enacted, repealed or amended, (c) any reference herein to any Person shall be construed to include the Person's successors and assigns, (d) all references herein to Articles, Sections, Exhibits or Schedules, unless otherwise specifically provided, shall be construed to refer to Articles, Sections, Exhibits or Schedules of this Agreement and (e) the word "will" shall be construed to have the same meaning and effect as the word "shall". References to any Sections include Sections and subsections that are part of the Section (e.g., a section numbered "Section 2.2(a)" would be part of "Article 2", and references to "Section 2.2(a)" would also refer to material contained in the subsection described as "Section 2.2(a)(i)").
- 17.11.3 Headings and captions are for convenience only and are not to be used in the interpretation of this Agreement.

17.11.4 Whenever any provision of this Agreement uses the term "including" (or "includes"), such term will be deemed to mean "including without limitation" (or "includes without limitation") and the term "or" is used in the inclusive sense (and/or). "Herein," "hereby," "hereunder," "hereof" and other equivalent words refer to this Agreement as an entirety and not solely to the particular portion of this Agreement in which any such word is used. In addition: (i) words in the singular or plural form include the plural and singular form, respectively; (ii) whenever this Agreement refers to a number of days, such number will refer to calendar days unless Business Days are specified; (iii) when a time period set forth in this Agreement ends on a day that is not a Business Day, the last day of such time period shall be the next Business Day; and (iv) all words used in this Agreement will be construed to be of such gender or number as the circumstances require. All definitions set forth herein will be deemed applicable whether the words defined are used herein in the singular or the plural.

Competition Law Filings. Within at least [\*\*\*] Business Days of its receipt of written notice from 17.12 Janssen with respect to the Competition Law Filings, as applicable, in connection with (i) the exercise of a Commercial Option pursuant to Section 4.3 or (ii) [\*\*\*], at the request of Janssen, Fate will, in consultation and cooperation with Janssen, file or submit, and assist Janssen with any Competition Law Filing necessary or advisable in connection with the U.S. Federal Trade Commission (the "FTC") and the U.S. Department of Justice (the "DOJ") under the HSR Act and the appropriate governmental entity under any other applicable Competition Law. Any such Competition Law Filings made by each of Janssen and Fate will be in substantial compliance with the requirements of the Competition Laws. Each of Janssen and Fate will use its reasonable efforts, and cooperate with each other, to obtain as promptly as practicable all approvals, authorizations, terminations of applicable periods and clearances in connection with the Competition Law Filings, including (a) cooperating and consulting with each other and furnishing to each other or each other's counsel information and reasonable assistance as each may request in connection with the preparation of any Competition Law Filing, (b) giving the other reasonable prior notice of, and the opportunity to review and discuss in advance (including considering in good faith the views of the other), any such Competition Law Filings to be made and, to the extent reasonably practicable, of any communication with, or any responses to inquiries or requests for additional information from, the FTC, the DOJ and any other governmental entity regarding such Competition Law Filings or the transactions contemplated by the Commercial Option or the [\*\*\*], as applicable, (c) permitting the other or the other's counsel to participate in all material communications and meetings with any governmental entity to the extent not prohibited by such governmental entity and (d) subject to clauses (b) and (c) of this Section 17.12, responding as promptly as practicable to all requests of any governmental entity and providing all requested information to such governmental entity. Janssen and Fate will each pay their own expenses and attorneys' fees associated with any Competition Law Filings (including any response to requests for additional information); however, Janssen will pay any filing fees required with the Competition Law Filings relating to the exercise of the Commercial Option, and Fate will pay any filing fees required with the Competition Law Filings relating to the [\*\*\*] by Fate.

- **17.13 Performance by Affiliates**. Each Party shall always have the right to perform any or all of its obligations and exercise any or all of its rights under this Agreement through any of its Affiliates (but only for so long as such entity remains an Affiliate of such Party), *provided* that each Party shall remain responsible for the performance of this Agreement and the compliance with the terms and conditions of this Agreement by its Affiliates and any act or omission by an Affiliate of such Party shall constitute an act or omission by such Party.
- **17.14 Effects of Fate Change of Control**. In the event of the occurrence of a Change of Control of Fate during the Term, the following provisions of this Section 17.14 shall apply:



- **17.14.2 Competing Products**. If the Acquirer or any of its Affiliates is Developing or Commercializing a Competing Product in the Field, then the Acquirer shall Segregate the program and activities related to such Competing Product, including by:
- (a) adopting reasonable procedures to prevent the Acquirer's use of Confidential Information relating to the Collaboration Candidates or Licensed Products in the exploitation of such Competing Product;
- **(b)** using [\*\*\*] Efforts to ensure that no personnel working on the program and activities related to such Competing Product have access to non-public clinical data or technical Know-How, or the marketing and commercialization plans, relating to the Collaboration Candidates or Licensed Products being Developed or Commercialized by the Parties under this Agreement;
- (c) using [\*\*\*] Efforts to ensure that no personnel working on the program and activities related to the Collaboration Candidates or Licensed Products have access to non-public clinical data or technical Know-How, or the marketing and commercialization plans, relating to such Competing Product; and
- **(d)** requiring employees and contractors of the Acquirer who have day-to-day responsibilities for such Competing Product to recuse themselves from meetings and conference calls between Fate and Janssen relating to this Agreement if such Competing Product is expected to be discussed during such meeting or call.

17.14.3		[***]
	(a)	[***]
	<b>(b)</b>	[***]
	(c)	[***]
	(d)	[***]
	(e)	[***]
	<b>(f)</b>	[***]
	(g)	[***]
	(h)	[***]
	(i)	[***]
	(j)	[***]

17.15 Counterparts; Electronic Delivery. This Agreement may be executed in counterparts with the same effect as if both Parties had signed the same document. All such counterparts shall be deemed an original, shall be construed together and shall constitute one and the same instrument. Signatures to this Agreement transmitted by facsimile, by email in "portable document format" (".pdf"), or by any other electronic means intended to preserve the original graphic and pictorial appearance of this Agreement shall have the same effect as physical delivery of the paper document bearing original signature.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have caused this Collaboration and Option Agreement to be executed by their respective duly authorized officers as of the Effective Date.

FATE TE	ierapeutics, Inc.	Janssen Biotech, Inc.			
By:	/s/ J. Scott Wolchko	By:	/s/ Thomas Cavanaugh		
Name:	J. Scott Wolchko	Name:	Thomas Cavanaugh		
Title:	President and Chief Executive_Officer		President		

#### LIST OF EXHIBITS AND SCHEDULES

Exhibit 1.10	Janssen Parent Universal Calendar
Exhibit 3.2.2	Reserved Antigens
Exhibit 3.3.3	Research Responsibilities
Exhibit 3.3.4	Research Plans for Janssen Antigen 1 and Janssen Antigen 2
Exhibit 6.4	Profit Share Product Exhibit
Exhibit 11.7.1	Existing Agreements
Exhibits 12.9.1	Press Release
Exhibit 13.2.1	Fate Research Patents
Schedule 5.3	Fate Confidential Methods
Schedule 5.3.7	Janssen Confidential Methods
Schedule 10.6.2	Fate Licensor Patents
Schedule 13.2.11	Exclusions

### **EXHIBIT 1.10**

	[***]	[***]	[***]	[***]	[***]	[***]	[***]		[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***] [***]	[***] [***]	[***] [***] [***]	[***] [***]	[***] [***]	[***] [***]	[***] [***]	[***] [***] [***]	[***]	[***] [***]	[***] [***]	[***] [***]	[***] [***]	[***] [***]	[***] [***] [***]	[***] [***] [***]
	[***]	[***]	[***]	[***]	[***]	[***]	[***]		[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***] [***] [***]	[***] [***] [***]	[***] [***] [***]	[***] [***] [***]	[***] [***] [***]	[***] [***] [***]	[***] [***]	[***]	[***] [***]	[***] [***] [***]	[***] [***] [***]	[***] [***] [***]	[***] [***] [***]	[***] [***] [***]	[***] [***] [***]
	[***]	[***]	[***]	[***]	[***]	[***]	[***]		[***] [***]	[***]	[***]	[***]	[***]	[***]	[***]
[***] [***]	[***] [***] [***]	[***] [***]	[***] [***]	[***] [***] [***]	[***] [***] [***]	[***] [***] [***]	[***] [***] [***]	[***] [***] [***]	[***] [***] [***]						
[***] [***]	[***] [***] [***]	[***] [***]	[***] [***] [***]	[***] [***] [***]	[***] [***] [***]	[***] [***] [***]	[***] [***] [***]	[***] [***] [***]	[***] [***] [***]						
[***]	[***] [***] [***]	[***] [***] [***]	[***] [***] [***]	[***] [***] [***]	[***] [***] [***]	[***] [***] [***]	[***] [***] [***]	[***] [***]	[***] [***] [***]	[***] [***] [***]	[***] [***] [***]	[***] [***] [***]	[***] [***] [***]	[***] [***] [***]	[***] [***] [***]
	[***]	[***]	[***]	[***]	[***]	[***]	[***]		[***] [***]	[***]	[***]	[***]	[***]	[***]	[***]
[***] [***]	[***] [***] [***]	[***] [***]	[***] [***] [***]	[***] [***] [***] [***]	[***] [***] [***] [***]	[***] [***] [***] [***]	[***] [***] [***] [***]	[***] [***] [***] [***]	[***] [***] [***]						

### EXHIBIT 3.2.2 Reserved Antigens

[\*\*\*]

### EXHIBIT 3.3.3 Research Responsibilities

[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
		[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

[\*\*\*

[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

 $\underline{EXHIBIT\ 3.3.4}$  Research Plans for Janssen Antigen 1 and Janssen Antigen 2

#### **EXHIBIT 3.3.4**

#### The Initial Research Plan

[\*\*\*]

# EXHIBIT 6.4 Profit Share Product Exhibit

#### **EXHIBIT 6.4**

#### PROFIT SHARE PRODUCT EXHIBIT

The terms set forth in this **Exhibit 6.4** shall apply with respect to each Profit Share Product beginning on the Opt-In Exercise Date and for the remainder of the Profit Share Term, subject to the terms of the Agreement. Unless the context requires otherwise, references in this Exhibit to a Section refer to the applicable Section of this Exhibit, not the Agreement.

#### ARTICLE I DEFINITIONS

As used in this **Exhibit 6.4**, the following terms shall have the meanings set forth below:

- **1.1** "**Collaboration Indication**" means any Indication that is or has been the subject of a Clinical Trial in the GDP for the Profit Share Product.
- **1.2** "Combination Regimen" means the administration of two or more drugs or biological products together for the treatment, diagnosis or prophylaxis of any Indication, including a Licensed Product and at least one other distinct drug or biological product that is not a Licensed Product, where such Licensed Product and other drug or biological product are (i) separately presented or packaged, (ii) sold separately and (iii) labelled for use together for the treatment, diagnosis or prophylaxis of such Indication.
- **1.3** "Commercial FTE" means [\*\*\*] hours of work devoted to or in direct support of the Commercialization of the Profit Share Product in the U.S. (and, with respect to Commercial FTE Costs that are included in Allocable Global Costs, in both the U.S. and the OUS Territory) that is carried out by one or more qualified employees, contractors or consultants of a Party or its Affiliates, *provided* that one individual conducting more than [\*\*\*] hours of work in any Calendar Year will not be considered more than one Commercial FTE and, in the case of work by an individual that is less than [\*\*\*] hours, will be prorated based on the actual number of hours expended by such individual. Commercial FTE shall not include personnel performing administrative and corporate functions (including human resources, finance, legal and investor relations), [\*\*\*].
- **1.4** "Commercial FTE Costs" means, with respect to any period, the amount calculated by multiplying [\*\*\*] by [\*\*\*]; *provided*, *however*, that Commercial FTE Costs for sales representatives shall be calculated as set forth in the definition of Selling Costs in the Financial Exhibit.

#### **1.5** "Commercial FTE Rate" means:

(a) with respect to any Commercial FTE other than a sales representative, [\*\*\*]% of the gross salaries (not including any bonus or other performance-based incentive payments) of a Party's or its Affiliates' employees, contractors or consultants who perform Commercialization activities with respect to the Profit Share Product in the U.S. (and, with respect to Commercial FTE Costs that are included in the Allocable Global Costs, in both the U.S. and the OUS Territory); and

(b) with respect to any Commercial FTE that is a sales representative, [\*\*\*]% of the gross salaries of a Party's or its Affiliates' sales representatives who Detail the Profit Share Product in the U.S. (including (x) any cash bonus or other performance-based cash incentive payments, to the extent based directly on sales or promotion of the Profit Share Product (and not other products), and (y) any cash bonus tied to the overall performance of an individual sales representative, but not based on sales or promotion of the Profit Share Product or any other products).

The Commercial FTE Rate is "fully burdened" and will cover any automobile allowance, meal expenses, travel/housing for meetings, benefits (including non-working time), facilities, utilities, information technology, insurance and other incidental expenses incurred by such personnel in the ordinary course of employment (i.e., such amounts shall not be considered "salary" and shall not be considered Out-of-Pocket Expenses, but shall be included in, and deemed reimbursed by means of, the Commercial FTE Rate).

- **1.6** "**CPI**" means the Consumer Price Index-Urban Wage Earners and Clerical Workers, U.S. City Average, All Items, 1982-1984=100, published by the U.S. Department of Labor, Bureau of Labor Statistics (or its successor equivalent index) in the U.S.
- 1.7 "Development FTE" means [\*\*\*] hours of work devoted to or in direct support of the Development of the Profit Share Product that is carried out by one or more qualified employees or contractors or consultants of a Party or its Affiliates, *provided* that one individual conducting more than [\*\*\*] hours of work in any Calendar Year will not be considered more than one Development FTE and, in the case of work by an individual that is less than [\*\*\*] hours, will be pro-rated based on the actual number of hours expended by such individual. Development FTE includes scientific, medical, technical and other personnel directly engaged in performing Development activities with respect to the Profit Share Product (including the project management teams that support the Profit Share Product). Development FTE shall not include work performed by personnel performing administrative and corporate functions (including human resources, finance, legal and investor relations).
  - **1.8** "**Development FTE Costs**" means, with respect to any period, the amount calculated by multiplying [\*\*\*].
- **1.9** "**Development FTE Rate**" means a rate of [\*\*\*] per full-time Development FTE per Calendar Year; *provided*, *however*, that such rate shall be increased or decreased annually beginning on [\*\*\*] by the percentage increase or decrease in the CPI between the last day of the most recently completed Calendar Year and [\*\*\*], plus [\*\*\*] or an alternative methodology that is mutually agreed to by both Parties. The Development FTE Rate is "fully burdened" and will cover employee salaries (excluding stock-based compensation), benefits, utilities, facilities, and travel expenses.
- **1.10** "**Drug Regulation Laws**" means Laws regulating drugs and biological products, including the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et. seq.*, the Public Health Service Act and regulations issued by the FDA, each as in effect and as amended from time to time, and similar Laws in the OUS Territory, each as in effect and as amended from time to time.

- **1.11** "Fate Housemarks" means (a) the corporate logo of Fate, (b) the trademark "Fate", (c) any other trademark, trade name or service mark (whether registered or unregistered) of Fate or its Affiliates that is not a Product Trademark, and (d) all intellectual property rights residing in any of the foregoing.
- **1.12 "Financial Exhibit"** means **Exhibit 1.12-1** attached hereto, as the same may be amended from time to time by the Parties.
- **1.13** "Government Health Care Programs" means the Medicare program (Title XVIII of the Social Security Act), the Medicaid program (Title XIX of the Social Security Act), TRICARE, the Federal Employees Health Benefits Program, and other foreign, federal, state and local governmental health care plans and programs.
- 1.14 "Health Care Laws" means Laws relating to Government Health Care Programs, Private Health Care Plans, privacy and confidentiality of patient health information and human biological materials, including, in the United States, federal and state Laws pertaining to the federal Medicare and Medicaid programs (including the Medicaid rebate program); federal Laws pertaining to the Federal Employees Health Benefits Program, the TRICARE program and other Government Health Care Programs; federal and state Laws applicable to health care fraud and abuse, kickbacks, physician self-referral and false claims (including 42 U.S.C. § 1320a-7a, 42 U.S.C. § 1320a-7b, 42 U.S.C. § 1395nn and the federal Civil False Claims Act, 31 U.S.C. § 3729 et. seq.); the Health Insurance Portability and Accountability Act of 1996; and 45 C.F.R. Part 46, and similar Laws in the OUS Territory, each as in effect and as amended from time to time.
- **1.15** "Janssen Housemarks" means (i) the corporate logo of Janssen, (ii) the trademark "Janssen", (iii) any other trademark, trade name or service mark (whether registered or unregistered) of Janssen or its Affiliates that is not a Product Trademark, and (iv) all intellectual property rights residing in any of the foregoing.
- **1.16** "Janssen Profit Share Product Know-How" means all Know-How Controlled by Janssen or its Affiliates as of the Effective Date or at any time during the Term that is reasonably necessary or useful for the Commercialization of the Profit Share Product.
- **1.17 "Janssen Profit Share Product Patents"** means all Patents Controlled by Janssen or its Affiliates as of the Effective Date or at any time during the Term that cover the Commercialization of the Profit Share Product.
- **1.18** "**Private Health Care Plans**" means non-governmental Third Party health care payors and plans, including insurance companies, health maintenance organizations and other managed care organizations, Blue Cross and Blue Shield plans and self-funded employers.
- **1.19 "Shared CMC Development Costs"** means CMC Development Costs incurred by the Parties and their Affiliates with respect to the Profit Share Product under the CMC Development Plan.

1.20	"Shared De	velopment	Costs" means	Developmen	FTE Costs	and Out-of-I	Ocket Expenses	incurred by
the Parties and their	Affiliates in	conducting	Development	activities wit	h respect to	the Profit Sh	are Product und	ler the GDP
including:								

(a) all Development FTE Costs and Out-of-Pocket Expenses incurred for activities specified in the GDP;

- **(b)** with respect to non-clinical and clinical research and drug development activities for the Profit Share Product (including Clinical Trials), the Cost of Goods for Profit Share Product and other drugs, biological products or devices used in such Clinical Trials (including Development FTE Costs and Out-of-Pocket Expenses to purchase or package Third Party drugs, biological products and devices) and Development FTE Costs and Out-of-Pocket Expenses for disposal of clinical samples;
- (c) with respect to regulatory activities for the Profit Share Product, Development FTE Costs and Out-of-Pocket Expenses for fees incurred in connection with Regulatory Filings and Regulatory Approvals and for meetings with Regulatory Authorities;
- **(d)** any other Development FTE Costs and Out-of-Pocket Expenses incurred that are expressly included in the Development Budget; and

(e) [\*\*\*].

Shared Development Costs for Combination Products and Combination Regimens that include a product (other than a Profit Share Product) to which Janssen or its Affiliates has any rights, including other drugs, biological products or devices used in such Clinical Trials referred to in Section 1.20(b), will be allocated by the JFC between such other product and the Profit Share Product, and only the amounts allocated to the Profit Share Product will be included in the Development Budget and as Shared Development Costs for purposes of Fate's payment obligations hereunder. Shared Development Costs are not included in Allowable Expenses for purposes of calculating U.S. Pre-Tax Profits and Losses, and are separate from, and do not include, (i) Research Costs, (ii) any payments made pursuant to Section 6.1, 6.2, 6.4 or 6.5 of this Exhibit, (iii) capital expenditures, (iv) Shared CMC Development Costs or (v) costs attributable to general corporate activities, executive management, investor relations, treasury services, business development, corporate government relations, finance, and other overhead.

# **1.21 Additional Definitions**. The definitions of each of the following terms is set forth in the Section of this **Exhibit 6.4** indicated below:

<u>Definition</u>		<u>Section</u>
1.	Allocable Global Costs	5.1.2(b)
2.	Allowable Expenses	Financial Exhibit
3.	Charitable Contribution Costs	Financial Exhibit
4.	Collaboration Losses	Financial Exhibit
 5.	Commercialization Wind-Down Period	9.1.2(i)
6.	Controlling Party	8.1.5
7.	Cost Report	6.3.3(c)
8.	Data Costs	Financial Exhibit
9.	Detail	Financial Exhibit
10.	Development Budget	4.1.2(b)
11.	Development Reconciliation Procedures	6.3.3(b)
12.	Distribution Costs	Financial Exhibit
13.	First Position Detail	Financial Exhibit
14.	Global Development Plan or GDP	4.1.1
15.	Health Care Reform Fees	Financial Exhibit
16.	Inventory	9.1.2(f)
17.	Janssen Development Costs	6.3.2
18.	Joint Development Committee or JDC	2.2
19.	Joint Finance Committee or JFC	2.4
20.	Marketing Expenses	Financial Exhibit
21.	Medical Affairs Expenses	Financial Exhibit
22.	[***]	I munciai Exmort
23.	[***]	
24.	Other Commercialization Costs	Financial Exhibit
25.	Other Income	Financial Exhibit
26.	Product Liability Costs	8.1.1
27.	Profit Share Regulatory Milestone Event	6.1.2
28.	Profit Share Sales Milestone Event	6.2.2
29.	Project Management, Alliance Management and Healthcare Compliance (HCC) Costs	Financial Exhibit
30.	Recall Expenses	Financial Exhibit
31.	Regulatory Maintenance Costs	Financial Exhibit
32.	Reverted Profit Share Product	9.1.1(a)
33.	Second Position Detail	Financial Exhibit
34.	Selling Costs	Financial Exhibit
3 <del>5</del> .	Shared Product Liability Costs	8.1.2
36.	Shared Troduct Elability Costs Shared Third Party Products Liability Action	8.1.4
37.	Supply Costs	Financial Exhibit
37. 38.	Third Party Products Liability Action	8.1.4
36. 39.	Third Position Detail	6.1.4 Financial Exhibit
40.	U.S. Commercialization Budget	5.1.2(b)
40. 41.	U.S. Commercialization Option	* *
<del>+</del> 1,	O.O. Commercianzation Option	5.1.3(b)

42.	U.S. Commercialization Plan	5.1.1
43.	U.S. Joint Commercialization Committee or USJCC	2.3
44.	U.S. Pre-Tax Loss	Financial Exhibit
45.	U.S. Pre-Tax Profit	Financial Exhibit
46.	U.S. Pre-Tax Profits and Losses	Financial Exhibit
<i>4</i> 7	U.S. Reconciliation Procedures	6.4.2

#### ARTICLE II Governance

- **2.1 Joint Steering Committee.** Section 2.3.2 of the Agreement shall no longer apply with respect to the Profit Share Product and, instead, the JSC's responsibilities with respect to the Profit Share Product shall be to: (i) review and approve the GDP, the Development Budget, the U.S. Commercialization Plan, the U.S. Commercialization Budget and any other budgets with respect to the Profit Share Product in accordance with Sections 4.1.3 and 5.1.2 of this Exhibit; (ii) resolve Committee Matters on which the Committees do not reach consensus in accordance with Section 2.6 of this Exhibit; and (iii) perform the other functions with respect to the Profit Share Product that are expressly delegated to the JSC in this Exhibit. The JSC shall have no authority with respect to Commercialization of the Profit Share Product in the OUS Territory, *provided* that the JSC shall have the authority to review and discuss, but not approve, the global commercialization strategy in accordance with Section 5.1.2(e) and the JSC shall serve as a forum for discussions regarding Janssen's Commercialization of the Profit Share Product in the OUS Territory as described in this Exhibit.
- **2.2 Joint Development Committee.** The Parties shall establish a joint Development committee (the "**Joint Development Committee**" or "**JDC**") to: (i) oversee, and make decisions with respect to Janssen's Development of the Profit Share Product in the U.S. and OUS Territory pursuant to Article IV of this Exhibit; and (ii) perform the other functions with respect to the Profit Share Product that are expressly delegated to the JDC in this Exhibit. The JDC shall be composed of at least three (3) employee representatives of each Party, each with scientific and technical capabilities to carry out the responsibilities of the JDC and sufficient seniority within the applicable Party to make decisions arising with the scope of the JDC's responsibilities. Each Party may change its JDC representatives from time to time in its sole discretion, effective upon written notice to the other Party of such change. The Parties shall use [\*\*\*] Efforts to establish the JDC within [\*\*\*] days after the Opt-In Exercise Date for the first Profit Share Product.

- 2.3 U.S. Joint Commercialization Committee. The Parties shall establish a joint U.S. commercialization committee (the "U.S. Joint Commercialization Committee" or "USJCC") to: (i) oversee and make decisions with respect to the Parties' Commercialization of the Profit Share Product in the U.S. pursuant to Article V of this Exhibit, including an allocation of activities to Fate if Fate exercises the U.S. Commercialization Option; and (ii) perform the other functions with respect to the Profit Share Product that are expressly delegated to the USJCC in this Exhibit. The USJCC shall be composed of at least three (3) employee representatives of each Party, each with experience with commercialization of similar pharmaceutical products sufficient to carry out the responsibilities of the USJCC and sufficient seniority within the applicable Party to make decisions arising with the scope of the USJCC's responsibilities. Each Party may change its USJCC representatives from time to time in its sole discretion, effective upon written notice to the other Party of such change. The Parties shall use [\*\*\*] Efforts to establish the USJCC no later than [\*\*\*] months prior to the anticipated launch of the first Profit Share Product in the U.S. If this Exhibit requires that any decision be made by the USJCC before it is formed, such decision shall be made by the JSC.
- **2.4 Joint Finance Committee.** The Parties shall establish a joint finance committee (the "**Joint Finance Committee**" or "**JFC**") to: (i) coordinate and conduct the budgeting, accounting, reporting, reconciliation and other financial activities with respect to the Profit Share Product to the extent provided in this Exhibit; (ii) if requested by the JSC, develop and recommend to the JSC for approval a process for the development and approval of budgets contemplated by this Exhibit; and (iii) perform the other functions with respect to the Profit Share Product that are expressly delegated to the JFC in this Exhibit. The JFC shall be composed of at least three (3) employee representatives of each Party, each with reasonable expertise in the areas of accounting, cost allocation, budgeting and financial reporting and sufficient seniority within the applicable Party to make decisions arising with the scope of the JFC's responsibilities. The Parties shall use [\*\*\*] Efforts to establish the JFC within [\*\*\*] days after the Opt-In Exercise Date for the first Profit Share Product.
- **2.5 Joint Manufacturing Committee**. The JMC will continue to have the responsibilities and authority relating to the Profit Share Product set forth in the Agreement.

#### 2.6 Decision-Making.

- **2.6.1** The JDC, USJCC and JFC shall determine, approve or resolve Committee Matters by unanimous consensus, with each Party's representatives on the applicable Committee collectively having one (1) vote. The JMC will continue to make decisions in accordance with Section 2.2.3 of the Agreement, except as described in this Section 2.6.
- **2.6.2** If, after reasonable discussion and good faith consideration of each Party's comments on a particular Committee Matter, the JDC, USJCC, JFC or JMC does not reach consensus on any Committee Matter within its authority within [\*\*\*] days after such matter is first presented to such Committee, either Party may refer such Committee Matter to the JSC for resolution.

- **2.6.3** If, after reasonable discussion and good faith consideration of each Party's comments on a particular Committee Matter, the JSC does not reach consensus (either with respect to any Committee Matter referred to it by the JDC, USJCC, JFC or JMC or with respect to any Committee Matter within the JSC's authority) within [\*\*\*] days after such Committee Matter is first presented to the JSC, then, unless this Exhibit expressly provides otherwise, either Party may refer such Committee Matter to the Executive Officers for resolution.
- **2.6.4** The Executive Officers shall use [\*\*\*] efforts to promptly resolve such matter, which good faith efforts shall include at least one teleconference between such Executive Officers within [\*\*\*] days after submission of such matter to them. If the Executive Officers do not reach consensus on a Committee Matter (other than a Committee Matter of the JMC) within [\*\*\*] days after such Committee Matter is referred to them, then [\*\*\*].
- **2.6.5** If the Executive Officers do not reach consensus with respect to a Committee Matter of the JFC within [\*\*\*] days after such matter is first presented to the Executive Officers, then either Party may refer such matter for resolution by [\*\*\*].
- **2.7 Additional Committee Rules**. The provisions of Sections 2.4, 2.5, 2.6 and 2.7 of the Agreement shall apply to the JDC, USJCC and JFC. If there is more than one Profit Share Product, there shall be only one of each Committee and such Committee's responsibilities and authority shall apply to all Profit Share Products, unless either Party requests otherwise. Consistent with Section 2.6 of the Agreement, for clarity, the following are not Committee Matters:

2.7.1	[***]
2.7.2	[***]
2.7.3	[***]
2.7.4	[***]
2.7.5	[***]

#### 2.8 Opt-Out.

**2.8.1** Fate shall have the right to terminate its rights and obligations set forth in this Exhibit with respect to the Profit Share Product by giving prior written notice to Janssen, such termination to be effective upon expiration of the Opt-Out Notice Period (such right, the "**Opt-Out**"). The "**Opt-Out Notice Period**" means the period beginning on the date of such notice and ending on the last day of the Calendar Quarter in which the [\*\*\*] anniversary of the date of such notice occurs; *provided*, *however*, that if Fate has exercised its U.S. Commercialization Option for the Profit Share Product, then such period will end on the last day of the Calendar Quarter in which the [\*\*\*] anniversary of the date of such notice occurs. The Parties may mutually agree to shorten the Opt-Out Notice Period. For example, if the Opt-Out notice is given on [\*\*\*] and Fate has not exercised its U.S. Commercialization Option, the [\*\*\*] anniversary of such date would be [\*\*\*] and the Opt-Out Notice Period would end on the last day of the [\*\*\*] of such Calendar Year.

- **2.8.2** During the Opt-Out Notice Period, the terms of this Exhibit shall continue to apply to the Profit Share Product, except that if Fate exercises the Opt-Out within sixty (60) days after [\*\*\*] exercises its [\*\*\*] under Section 2.6.4 to either (i) increase the aggregate amount of the Development Budget for the then-current Calendar Year or (ii) approve a Development Budget for the next Calendar Year in which the aggregate amount of the Development Budget for the first Calendar Year (i.e. the binding portion) is greater than the forecasted amount set forth in the then-current Development Budget for such Calendar Year, then in the case of either (i) or (ii) the incremental amount of the increase approved by [\*\*\*] shall be excluded from Shared Development Costs for purposes of Section 6.3 during the Opt-Out Notice Period.
- **2.8.3** During the Opt-Out Notice Period, the Parties will reasonably cooperate to conduct all activities necessary to transition all responsibilities of Fate with respect to the Commercialization (but not Manufacture) of the applicable Profit Share Product in the U.S. to Janssen on a timely basis.
- **2.8.4** Upon the expiration of the Opt-Out Notice Period, the terms of this Exhibit shall no longer apply to the Profit Share Product, the applicable Licensed Product shall no longer be a Profit Share Product, and, subject to Section 6.2.6, the terms and conditions of the Agreement shall apply to such Licensed Product for the remainder of the Term; *provided*, *however*, that the [\*\*\*] upon expiration of the Opt-Out Notice Period.
- **2.8.5** Without limiting the foregoing, following the expiration of the Opt-Out Notice Period, (a) the Parties will [\*\*\*]. For clarity, Janssen shall have no obligation to reimburse Fate for any amounts paid by Fate to Janssen under Article VI of this Exhibit with respect to the Profit Share Product during the Profit Share Term or retroactively increase any Milestone Payment for any event that occurred with respect to the Profit Share Product during the Profit Share Term.

#### ARTICLE III LICENSE GRANTS

#### 3.1 Janssen Grants to Fate.

- **3.1.1** Commercialization License. Subject to the terms and conditions of the Agreement and this Exhibit, Janssen hereby grants, and shall cause its Affiliates to grant, to Fate, during the Profit Share Term for each Profit Share Product, a co-exclusive (with Janssen), non-transferable (except as permitted under Section 17.4 of the Agreement) license under the Janssen Profit Share Product Patents, Janssen Profit Share Product Know-How and the Product Trademarks, and sublicense under the Fate Product Patents and Fate Product Know-How exclusively licensed to Janssen under Section 5.1.2 of the Agreement, to sell, offer to sell, have sold, import and otherwise Commercialize the Profit Share Product in the Field in the U.S.
- **3.1.2** <u>Sublicensing.</u> The license granted by Janssen to Fate under this Section 3.1 shall be sublicensable only to the extent provided in Section 3.2.

- 3.1.3 <u>Definition of Co-Exclusive</u>. For purposes of this Section 3.1, "co-exclusive (with Janssen)" means that Janssen shall retain all of the same rights under the Janssen Profit Share Product Patents, Janssen Profit Share Product Know-How, Product Trademarks, Fate Product Patents and Fate Product Know-How to Commercialize the Profit Share Product in addition to Fate under Section 3.1.1, and Janssen covenants not to grant to any Third Party, without the prior written consent of Fate, a license under such retained rights to the Janssen Profit Share Product Patents, Janssen Profit Share Product Know-How, Product Trademarks, Fate Product Patents and Fate Product Know-How to conduct the applicable licensed activities with respect to the Profit Share Product in the U.S.
- **3.1.4** <u>Janssen Affiliates</u>. If any of the Janssen Profit Share Product Patents, Janssen Profit Share Product Know-How, Product Trademarks, Fate Product Patents or Fate Product Know-How licensed by Janssen to Fate pursuant to this Section 3.1 is Controlled by an Affiliate of Janssen, Janssen shall procure that such Affiliate grants the licenses to Fate in accordance with this Section 3.1.
- **3.2 Sublicensing.** Fate shall have the right to grant sublicenses of the license granted to Fate pursuant to Section 3.1.1 to any of its Affiliates without the consent of Janssen; *provided*, *however*, that Fate shall not grant such a sublicense if such grant would cause adverse tax consequences to Janssen (or Janssen's Affiliates), as reasonably demonstrated by Janssen within [\*\*\*] Business Days of being notified of a proposed sublicense. In the event a sublicense would so cause such adverse tax consequences, the Parties agree to cooperate reasonably to enable such sublicense [\*\*\*].

#### ARTICLE IV DEVELOPMENT

[\*\*\*] the following terms of this Article IV shall apply to the Development of the Profit Share Product during the Profit Share Term:

#### 4.1 GDP and Development Budget.

**4.1.1** General. Janssen shall conduct Development of the Profit Share Product in accordance with the Global Development Plan. "Global Development Plan" or "GDP" means the written plan for Janssen's Development of the Profit Share Product in the U.S. and OUS Territory containing the information set forth in Section 4.1.2 below, as it may be amended from time to time in accordance with the terms of this Exhibit. The GDP shall include the Development Budget, as described in Section 4.1.2 below. If there is more than one Profit Share Product, each Profit Share Product shall have a separate GDP.

#### **4.1.2** GDP Contents.

(a) Each GDP shall include, with respect to the applicable Profit Share Product and each Collaboration Indication for such Profit Share Product, all Development activities that are reasonably necessary to seek, obtain and maintain Commercialization Approval, and to support and sustain Commercialization, of the Profit Share Product for such Collaboration Indication in the U.S. and OUS Territory. Each GDP shall at all times reflect [\*\*\*] Efforts to [\*\*\*].

<b>(b)</b> T	The GDP shall include a rolling, [***] budget for Shared Development Costs to be
incurred by Janssen in conducting the I	Development activities described in the GDP that are scheduled to be commenced or
conducted during the [***], the "Develop	pment Budget"). The Development Budget shall be broken down by Development FTE
Costs and Out-of-Pocket Expenses by C	Clinical Trial by Calendar Year and Calendar Quarter for the [***]. The [***] of each
Development Budget shall be [***], and t	the [***] of such Development Budget shall serve as [***].
(c) F	For each Collaboration Indication in the GDP the GDP shall include Medical Affairs

- (c) For each Collaboration Indication in the GDP, the GDP shall include Medical Affairs Studies that are reasonably necessary to seek, obtain and maintain pricing and reimbursement approvals for, and to support and sustain Commercialization of, the Profit Share Product for such Collaboration Indication in the U.S. and OUS Territory. Following Marketing Approval of the Profit Share Product for an initial Collaboration Indication, the GDP may also include IISs, Cooperative Group Studies and Real World Evidence (RWE) studies to support Marketing Approval of the Profit Share Product for other Collaboration Indications in the U.S. and OUS Territory. Each Development Budget shall include an amount for Medical Affairs Studies for each [\*\*\*] covered by such Development Budget.
- (d) Notwithstanding the foregoing, the GDP will not include CMC Development activities for the Profit Share Product. Such activities will be included in and governed by the CMC Development Plan for the Profit Share Product.

#### **4.1.3** <u>Initial GDP; Updates and Amendments.</u>

- (a) The clinical development plan and budget included in the POC Data Package delivered by Janssen to Fate in accordance with Section 6.2 of the Agreement shall be the initial GDP and Development Budget for the Profit Share Product. For clarity, such initial GDP and Development Budget for the Profit Share Product shall cover the [\*\*\*]. If Janssen desires to make changes to such initial GDP and Development Budget, then Janssen may submit a proposed update or amendment to the GDP in accordance with Section 4.1.3(d) of this Exhibit. The GDP (including the Development Budget) may be updated and amended from time to time only with the approval of the JSC, as described below in this Section 4.1.3.
- **(b)** The JDC shall review the GDP annually and prepare any recommended updates. No later than [\*\*\*] of the then-current Calendar Year, the JDC shall prepare an updated GDP (excluding the Development Budget). No later than [\*\*\*] of the then-current Calendar Year, the JDC shall prepare an updated Development Budget covering each of the [\*\*\*] (in accordance with Section 4.1.2(b)).
  - **(c)** The JDC shall submit all such updates to the JSC for review and approval, as follows:
  - (i) The JSC shall use reasonable efforts to grant preliminary approval of such updates no later than [\*\*\*] of each Calendar Year.
  - **(ii)** Promptly after the JSC's preliminary approval, such updates shall be submitted to each Party for its internal budgeting process.

(m) After each Party performs its internal budgeting process, the 35C shall use
reasonable efforts to grant final approval of such updates no later than [***] of each Calendar Year (or at a later time i
agreed by the JSC), at which time any approved updates shall be set forth in writing in an amended version of the GDP.
(d) Either Party may submit a proposed update or amendment to the GDP to the JDC from
time to time. The JDC shall discuss such proposal at its next meeting and make a recommendation to the JSC as to whether to
approve such update or amendment. The JDC may also independently develop proposed updates and amendments to the GDF

**(e)** If the JSC approves an update or amendment to the GDP (including any corresponding update or amendment to the Development Budget), the GDP (including the Development Budget) shall be deemed to be amended accordingly on the date of such approval. No update or amendment to the GDP shall become effective unless and until the JSC (or Executive Officers or Janssen, as applicable) approves a corresponding update or amendment to the Development Budget.

(f) [\*\*\*]

#### 4.2 Conduct of Development Activities.

which the JDC shall submit to the JSC for review and approval.

- **4.2.1** <u>General</u>. [\*\*\*] Janssen shall use [\*\*\*] Efforts to execute and to perform, or cause to be performed, the Development activities in the GDP for the Profit Share Product, in accordance with the timetables in the GDP.
- **4.2.2** <u>Allocation of Development Activities</u>. Janssen shall be solely responsible for conducting all Clinical Trials and all other Development activities in the GDP for the Profit Share Product.

#### **4.2.3** <u>Safety Concerns.</u>

- (a) Notwithstanding anything to the contrary in this Exhibit or the GDP, Janssen shall not be obligated to commence or continue a Clinical Trial of the Profit Share Product if Janssen reasonably determines that such Clinical Trial would pose an unacceptable safety or tolerability risk for the study subjects. Janssen shall so notify Fate of its determination and the Parties shall discuss the concerns in good faith to determine whether to terminate, suspend, modify or continue such Clinical Trial.
- **(b)** If Fate believes in good faith that termination or suspension of a Clinical Trial of the Profit Share Product is warranted because of safety or tolerability risks to the study subjects, then Fate shall so notify Janssen and the Parties shall discuss Fate's concerns in good faith to determine whether to terminate, suspend, modify or continue such Clinical Trial.
- **4.2.4** <u>Development Reports.</u> In advance of each meeting of the JDC, unless otherwise agreed between the Parties, Janssen will provide to the JDC a [\*\*\*].

**4.2.5** <u>Day-to-Day Responsibility.</u> Janssen shall be responsible for day-to-day implementation of the Development activities with respect to the Profit Share Product under the GDP and this Exhibit and shall have the right to make operational and administrative decisions with respect to how to implement such Development activities (e.g., with respect to a Clinical Trial, Janssen shall have the right to select and engage clinical trial sites), *provided* that such decisions shall not conflict with the GDP or any decision of the JDC or JSC with respect to such Development activity.

#### 4.3 Regulatory Cooperation.

- **4.3.1** Participation in Meetings. Subject to applicable Laws, Fate shall have the right to have one representative participate in all material meetings (including by telephone), conferences and discussions by Janssen or its Affiliate with Regulatory Authorities in the U.S. pertaining to Development of, or any Regulatory Filing for, the Profit Share Product. Janssen shall, to the extent feasible, provide Fate with reasonable advance notice of all such meetings and other contact and advance copies of all related documents (including Regulatory Filings) and other relevant information relating to such meetings or other contact.
- **4.3.2** Review of Regulatory Documentation. Janssen shall provide Fate with advance drafts of any material documents or other material correspondence pertaining to Regulatory Filings with respect to the Profit Share Product [\*\*\*], that Janssen plans to submit to any Regulatory Authority in the U.S. Fate may provide comments regarding such material documents and other material correspondence before their submission. [\*\*\*] Janssen shall provide Fate with copies of all material submissions it makes to, and all material correspondence (including written summaries of material oral correspondence) it receives from, a Regulatory Authority in the U.S. in accordance with this Section 4.3.2. Notices, copies of material submissions and material correspondence, and other materials to be given in advance as provided in this Section 4.3.2 shall be provided to Fate a reasonable time in advance in order to allow Fate a reasonable amount of time to review such notices, copies of submission and correspondence and materials before their submission to the applicable Regulatory Authority, and in any event at least [\*\*\*] Business Days in advance, unless circumstances necessitate a shorter time period. Material correspondence and other material documents received from a Regulatory Authority in the U.S. must be provided to Fate as soon as practicable, and in any event within [\*\*\*] Business Days.
- **4.3.3** OUS Territory Regulatory Activities. Janssen shall keep Fate regularly informed through the JDC regarding material regulatory activities with respect to the Profit Share Product in the OUS Territory. Janssen shall provide Fate with copies of all material submissions it makes to, and all material correspondence (including written summaries of material oral correspondence) it receives from, a Regulatory Authority in the Major Markets of the OUS Territory with respect to the Profit Share Product within [\*\*\*] days of any such submission or receipt, unless circumstances necessitate a shorter time period.

### ARTICLE V COMMERCIALIZATION

[\*\*\*] the following terms of this Article V shall apply to the Commercialization of the Profit Share Product during the Profit Share Term:

#### 5.1 Commercialization in the U.S.

**5.1.1** <u>General</u>. The Parties shall Commercialize each Profit Share Product in the U.S. in accordance with the applicable U.S. Commercialization Plan and the terms of this Section 5.1, subject to the oversight of the USJCC as set forth in this Section 5.1. "**U.S. Commercialization Plan**" means, for each Profit Share Product, a written plan for Commercialization of the Profit Share Product in the U.S. containing the information set out in Section 5.1.2 below, as it may be amended from time to time in accordance with the terms of this Exhibit. The U.S. Commercialization Plan shall include the U.S. Commercialization Budget, as described in Section 5.1.2 below.

#### 5.1.2 <u>U.S. Commercialization Plan.</u>

(a) Contents. The U.S. Commercialization Plan shall set forth the strategy for the Commercialization of the Profit Share Product in the U.S., the key Commercialization activities to be performed to implement such strategy, and the staffing requirements for each such Commercialization activity. If Fate exercises the U.S. Commercialization Option pursuant to Section 5.1.3 of this Exhibit, the U.S. Commercialization Plan shall allocate responsibility between the Parties for Commercialization activities with respect to the Profit Share Product in the U.S., which allocation shall be consistent with Section 5.1.3 of this Exhibit.

(b) *U.S. Commercialization Budget.* The U.S. Commercialization Plan shall include a [\*\*\*] rolling budget for Allowable Expenses to be incurred by the Parties in conducting Commercialization activities for the Profit Share Product in the U.S. pursuant to the U.S. Commercialization Plan during [\*\*\*] the "U.S. Commercialization Budget"). The U.S. Commercialization Budget shall include budgeted amounts for Commercial FTE Costs and Out-of-Pocket Expenses, broken down by Calendar Quarter for [\*\*\*], for Commercialization activities in the U.S. and a breakout of costs by functional area or category, as determined by the USJCC in conjunction with the JFC. The [\*\*\*] of the U.S. Commercialization Budget [\*\*\*] to the extent provided in the Financial Exhibit, and the [\*\*\*] shall serve as [\*\*\*] (subject to any other applicable restrictions in this Exhibit). Each U.S. Commercialization Budget shall also include an annual amount for strategic commercial efforts that will be undertaken by Janssen and its Affiliates at the global team level in accordance with the global commercialization strategy described in Section 5.1.2(e), of which [\*\*\*] percent ([\*\*\*]%) shall be allocable to the U.S. (the "Allocable Global Costs").

- (c) Initial U.S. Commercialization Plan; Annual Updates.
- (i) Janssen (and, if Fate exercises the U.S. Commercialization Option, Fate) shall prepare and develop the initial U.S. Commercialization Plan, which shall be submitted to the USJCC for review no later than [\*\*\*] months before the anticipated First Commercial Sale of the Profit Share Product in the U.S. The USJCC shall review, and submit to the JSC for approval, the initial U.S. Commercialization Plan no later than [\*\*\*] before the anticipated First Commercial Sale of the Profit Share Product in the U.S.
- (ii) Janssen (and, if Fate exercises the U.S. Commercialization Option, Fate) shall prepare and develop annual updates to the U.S. Commercialization Plan, which shall be submitted to the USJCC for review. The USJCC shall submit each updated U.S. Commercialization Plan to the JSC for review and approval in time to permit the JSC's preliminary approval to occur by no later than [\*\*\*] of the Calendar Year prior to the Calendar Year to which the proposed update relates. Upon the JSC's preliminary approval, such plan shall be submitted to each Party for its internal budgeting process with a target for final approval by the JSC no later than [\*\*\*] of the Calendar Year prior to the Calendar Year to which the proposed update relates (or at a later date if agreed by the JSC). After final approval by the JSC, such U.S. Commercialization Plan shall take effect on the first day of the Calendar Year to which such U.S. Commercialization Plan applies.
- (d) Amendments; Updates. Either Party may submit a proposed update or amendment to the U.S. Commercialization Plan to the other Party from time to time. The USJCC shall discuss such proposal at its next meeting and make a recommendation to the JSC as to whether to approve such update or amendment. The USJCC may also independently develop proposed updates and amendments to the U.S. Commercialization Plan, which the USJCC shall submit to the JSC for review and approval. [\*\*\*]
- (e) Global Commercialization Strategy. Fate acknowledges that Janssen's global commercialization strategy for the Profit Share Product will inform the U.S. Commercialization Plan. Janssen will develop, with input from Fate through its participation on the USJCC, the global commercialization strategy, which will set forth overall brand strategy/stewardship elements for the Profit Share Product, including brand name, trademarks, global positioning, global messaging, competitive readiness, life cycle management, and guidance for medical affairs and other functions. Janssen will provide the JSC with a copy of the global commercialization strategy and any updates on a quarterly basis, for review and discussion (but not approval) by the JSC.

#### **5.1.3** <u>U.S. Co-Commercialization Responsibilities</u>.

- (a) [\*\*\*] Each Party shall use [\*\*\*] Efforts to perform the Commercialization activities with respect to each Profit Share Product allocated to such Party in the applicable U.S. Commercialization Plan; *provided*, *however*, that if Fate does not exercise its U.S. Commercialization Option for any Profit Share Product, then Fate shall be relieved of its obligation to use [\*\*\*] Efforts with respect to such Profit Share Product under this Section.
- (b) With respect to Commercialization of each Profit Share Product in the U.S., Fate shall have the right to elect to perform: (x) up to [\*\*\*] percent ([\*\*\*]%) of the customer-facing efforts in the U.S. for the Profit Share Product (including selling, account management, product support, and MSLs, but excluding any other Medical Affairs Activities); and (y) up to [\*\*\*] percent ([\*\*\*]%) of home office functions in the U.S. for the Profit Share Product (including marketing, scientific communications, health economics research home office coordination role) and all other Commercialization activities for the Profit Share Product in the U.S., excluding, in each case ((x) and (y)), any efforts required to support activities Janssen has the exclusive responsibility to perform under Section 5.1.5 or 5.1.6 of this Exhibit (the "U.S. Commercialization Option"). In accordance with the percentages above, the USJCC will allocate responsibility for specific Commercialization activities for the Profit Share Product in the U.S. between the Parties to minimize redundancies and duplications between the Parties' respective responsibilities and resources in the U.S.
- (c) If Fate desires to exercise the U.S. Commercialization Option for any Profit Share Product, it shall give notice in writing to Janssen at least [\*\*\*] before the anticipated date of the first Marketing Approval of such Profit Share Product in the U.S., which notice shall specify the Commercialization activities Fate desires to perform and the percentage of such Commercialization activities that Fate desires to perform. If Fate so notifies Janssen, the U.S. Commercialization Plan shall be prepared and updated in accordance with Section 5.1.2 of this Exhibit and such U.S. Commercialization Plan will allocate activities consistent with Fate's election, *provided* that allocation of Commercialization activities shall be subject to Fate [\*\*\*]to perform such U.S. Commercialization activities. If requested by Fate, allocation of Commercialization activities to Fate may increase over time (up to the maximum levels of participation set forth above) and Janssen shall be responsible for conducting all activities set forth in the U.S. Commercialization Plan to the extent that they are not allocated to Fate. [\*\*\*]
- **(d)** To the extent permitted by applicable Law in the U.S., the packaging and labeling for the Profit Share Product in the U.S. will bear both the Janssen name and logo and the Fate name and Fate logo, and such names and logos will be presented with substantially equivalent prominence in any product presentations, exhibit booths, conferences, or promotion materials or activities.
- **5.1.4** <u>U.S. Commercialization Reports.</u> In advance of each meeting of the USJCC, unless otherwise agreed between the Parties, each Party will provide to the USJCC a [\*\*\*].

- **5.1.5** Booking Sales in U.S. Janssen and its Affiliates shall book all sales of the Profit Share Products in the U.S. and shall be solely responsible for all aspects of distribution of the Profit Share Products in the U.S. (including offering for sale, selling, importing, exporting, inventory management and control, storing, warehousing, transportation, all aspects of order processing, invoicing, collection of sales proceeds, booking of sales, preparation of sales records and reports, customer relations and services and handling of returns) and all pricing and reimbursement activities with respect to the Profit Share Product in the U.S. (including obtaining pricing and reimbursement approvals, conducting reimbursement/access services, conducting health policy/advocacy activities, determining prices charged and discounts offered, and conducting price calculations and related reporting to governmental authorities). If Fate receives any orders for Profit Share Product in the U.S., it shall refer such orders to Janssen.
- **5.1.6** <u>U.S. Pricing Matters</u>. Janssen shall be solely responsible for and have sole authority with respect to the prices charged and discounts, rebates and other sale and reimbursement terms and conditions for the Profit Share Products in the U.S. Janssen shall keep Fate reasonably informed through the USJCC of such matters. [\*\*\*].
- **5.1.7** <u>U.S. Recalls.</u> Janssen shall decide, in its sole discretion, whether to conduct a recall of any Profit Share Product in the U.S. and shall have sole discretion to determine the manner in which any such recall shall be conducted. Janssen shall notify Fate prior to commencing any recall and shall in good faith take into account any reasonable suggestions made by Fate in respect of such recall.
- **5.1.8** <u>U.S. Medical Inquiries</u>. Janssen shall handle all medical questions or inquiries from members of the medical profession in the U.S. regarding the Profit Share Products. Janssen shall keep Fate reasonably informed through the USJCC of any material medical question or inquiry from members of the medical profession in the U.S. regarding the Profit Share Products.

#### **5.1.9** <u>U.S. Commercialization Subcontracting.</u>

- (a) If Fate exercises the U.S. Commercialization Option for any Profit Share Product, then, if a Party desires to subcontract the performance of any Commercialization activities with respect to such Profit Share Product in the U.S., such Party shall so notify the other Party and the other Party shall have the right to elect to conduct such activities within [\*\*\*] days of such notice. If the other Party elects to conduct such activities, the USJCC shall update the U.S. Commercialization Plan accordingly. If the other Party does not elect to conduct such activities, then the Party may subcontract the performance of such activities to a Third Party in accordance with Section 7.7 of the Agreement, *provided* that the applicable Subcontractors satisfy any applicable Janssen standards that Janssen applies to subcontractors for its other products.
- **(b)** If Fate does not exercise the U.S. Commercialization Option for a particular Profit Share Product, then Janssen shall have the right to subcontract the performance of any Commercialization activities with respect to such Profit Share Product in the U.S. to a Third Party in accordance with Section 7.7 of the Agreement, *provided* that the applicable Subcontractors satisfy any applicable Janssen standards that Janssen applies to subcontractors for its other products.

#### **5.1.10** <u>U.S. Commercialization Compliance Matters.</u>

(a) Janssen shall develop relevant sales, promotion, market access and advertising materials relating to the Profit Share Products for use in the U.S. by both Parties and their Affiliates that comply with Janssen's applicable internal policies and procedures, the U.S. Commercialization Plans, and applicable Law and Regulatory Approvals.

(b) Each sales representative who details any Profit Share Product in the U.S. on behalf of either Party shall be an employee of such Party or one of its Affiliates; provided, however, that if Fate does not exercise the U.S. Commercialization Option with respect to a particular Profit Share Product, Janssen may engage a contract sales organization in accordance with Section 5.1.9(b) of this Exhibit. Janssen (and Fate, if Fate exercises the U.S. Commercialization Option for any Profit Share Product) shall each ensure that its and its Affiliates' sales representatives in the U.S. do not make any representation, statement, warranty or guaranty with respect to any Profit Share Product that is not consistent with the applicable, current package insert of prescribing information or other documentation accompanying or describing such Profit Share Product, including mutually approved limited warranty and disclaimers, if any. Janssen (and Fate, if Fate exercises the U.S. Commercialization Option for any Profit Share Product) shall each ensure that its and its Affiliates' sales representatives in the U.S. do not make any statements, claims or undertakings to any person with whom they discuss or promote the Profit Share Product that are not consistent with, nor provide or use any labeling, literature or other materials other than, those promotional materials developed and approved by Janssen. If at any time the use of specified promotional materials is no longer approved for the U.S., Janssen (and Fate, if Fate exercises the U.S. Commercialization Option for any Profit Share Product) shall as soon as practicable take action to remove the promotional materials from use by its and its Affiliates' sales representatives and destroy such materials.

(c) Janssen (and Fate, if Fate exercises the U.S. Commercialization Option for any Profit Share Product) shall each cause its and its Affiliates' sales representatives in the U.S. to comply with applicable Laws and guidelines related to the performance of its obligations under this Exhibit, including Health Care Laws, Drug Regulation Laws and all applicable regulations thereunder, the AMA and PhRMA Guidelines, and all relevant regulations, authorizations and local laws regarding advertisement, sale and promotion of pharmaceutical products and any relevant code of practice.

- Janssen (and Fate, if Fate exercises the U.S. Commercialization Option for any Profit (d) Share Product) shall ensure that its and its Affiliates' sales representatives perform details of the Profit Share Products in the U.S. in compliance with applicable Law, all of Janssen's reasonable instructions, the agreed quality and compliance standards, policies and guidelines relating to the Commercialization of the Profit Share Products and any corporate integrity agreement between Janssen and the HHS Office of Inspector General, Janssen (and Fate, if Fate exercises the U.S. Commercialization Option for any Profit Share Product) shall establish and maintain a compliance program that satisfies the seven elements for an effective compliance program set forth in the HHS Office of Inspector General's Compliance Program Guidance for Pharmaceutical Manufacturers, including designation of a compliance officer and the conduct of effective training and education. Fate shall maintain records and supporting documentation related to the subject matter of the Agreement in order to document or verify compliance with the provisions of this Section 5.1.10(d), and upon request of Janssen, up to once per year and upon reasonable advance notice, shall provide a Third Party auditor mutually acceptable to Fate with access to such records for purposes of verifying compliance with the provisions of this Section 5.1.10(d). Acceptance of a proposed Third Party auditor may not be unreasonably withheld by Fate. The costs related to the Third Party auditor will be paid by Janssen, and any auditing activities may not unduly interfere with the normal business operations of Fate. Fate may require the Third Party auditor to enter into a reasonable confidentiality agreement in connection with such an audit. Janssen (and Fate, if Fate exercises the U.S. Commercialization Option for any Profit Share Product) shall each be responsible for tracking and reporting transfers of value initiated and controlled by its and its Affiliates' employees, contractors and agents pursuant to the requirements of the marketing reporting laws or research expense reporting laws of any Governmental Authority, including Section 6002 of PPACA, commonly referred to as the "Sunshine Act."
- 5.1.11 <u>Day-to-Day Responsibility.</u> Janssen (and Fate, if Fate exercises the U.S. Commercialization Option for any Profit Share Product) shall be responsible for day-to-day implementation of the Commercialization activities with respect to the Profit Share Products in the U.S. for which it is assigned responsibility under the U.S. Commercialization Plans or this Exhibit and shall have the right to make operational and administrative decisions with respect to how to implement such Commercialization activities, *provided* that such decisions shall not conflict with the U.S. Commercialization Plans or any decision of the USJCC or JSC with respect to such Commercialization activity. For example purposes only (and such example shall have no impact on the allocation of U.S. Commercialization responsibilities under Section 5.1.3), with respect to sales representatives, if a Party is responsible under the U.S. Commercialization Plan for providing [\*\*\*] percent ([\*\*\*\*]%) of the sales representatives in the U.S. and the U.S. Commercialization Plan provides for a total of [\*\*\*\*] sales representatives in the U.S., such Party shall be responsible for hiring, training, deploying and managing [\*\*\*\*] sales representatives, but shall coordinate such efforts with the other Party.
- **5.2 Commercialization in the OUS Territory**. Janssen shall continue to have the sole right and authority, at its sole cost and expense, to Commercialize the Profit Share Products in the OUS Territory in accordance with Article 7 of the Agreement. [\*\*\*] Following [\*\*\*], Janssen shall use [\*\*\*] Efforts to [\*\*\*].

#### ARTICLE VI FINANCIAL PROVISIONS

#### 6.1 Regulatory Milestone Payments and Events.

- **6.1.1** Effect on Agreement. Section 10.4.2 of the Agreement shall not apply to the Profit Share Products. For clarity, Section 10.4.2 of the Agreement shall continue to apply to Related Licensed Products. In lieu of any milestone payments that would otherwise be due with respect to any Profit Share Product pursuant to Section 10.4.2 of the Agreement, Janssen shall pay to Fate milestone payments pursuant to Section 6.1.2 of this Exhibit for each Profit Share Product.
- **6.1.2** Profit Share Regulatory Milestone Events and Payments. In consideration of Fate's performance in achieving the following milestone events, Janssen shall pay to Fate the milestone payments set forth in the table below not later than [\*\*\*] days after Fate delivers an invoice to Janssen upon the first occurrence of the corresponding milestone event set forth below with respect to a Profit Share Product (each, a "**Profit Share Regulatory Milestone Event**"). For clarity, the milestone payments set forth in this Section 6.1.2 shall be payable for each Profit Share Product. Janssen shall provide notice to Fate within [\*\*\*] days after the occurrence of any of the Profit Share Regulatory Milestone Events:

Profit Share Regulatory Milestone Event	Milestone Payment			
	Janssen Antigen 1	Janssen Antigen 2	Janssen Antigen 3	Janssen Antigen 4
1. [***]	\$[***]	\$[***]	\$[***]	\$[***]
2. [***]	\$[***]	\$[***]	\$[***]	\$[***]
3. [***]	\$[***]	\$[***]	\$[***]	\$[***]
4. [***]	\$[***]	\$[***]	\$[***]	\$[***]
5. [***]	\$[***]	\$[***]	\$[***]	\$[***]
6. [***]	\$[***]	\$[***]	\$[***]	\$[***]
7. [***]	\$[***]	\$[***]	\$[***]	\$[***]
8. [***]	\$[***]	\$[***]	\$[***]	\$[***]
9. [***]	\$[***]	\$[***]	\$[***]	\$[***]
10. [***]	\$[***]	\$[***]	\$[***]	\$[***]
11. [***]	\$[***]	\$[***]	\$[***]	\$[***]
12. [***]	\$[***]	\$[***]	\$[***]	\$[***]
13. [***]	\$[***]	\$[***]	\$[***]	\$[***]
14. [***]	\$[***]	\$[***]	\$[***]	\$[***]
15. [***]	\$[***]	\$[***]	\$[***]	\$[***]
16. [***]	\$[***]	\$[***]	\$[***]	\$[***]
17. [***]	\$[***]	[***]	\$[***]	\$[***]
18. [***]	\$[***]	\$[***]	\$[***]	\$[***]

#### **6.1.3** <u>Milestone Conditions.</u>

- (a) The milestone payments under this Section 6.1 shall be non-refundable and non-creditable. [\*\*\*]
- **(b)** With respect to Profit Share Regulatory Milestone Events #11 through #18, such milestone events shall not be deemed to occur unless [\*\*\*].
- (c) If any of Profit Share Regulatory Milestone Events [\*\*\*] occurs for a particular Profit Share Product and Indication, and payment has not been made for Profit Share Regulatory Milestone Events [\*\*\*], respectively, for the same Profit Share Product and Indication, then such applicable payment for [\*\*\*].

### **6.2** Sales Milestone Payments.

- **6.2.1** Section 10.5 of the Agreement shall not apply to any Profit Share Product or, following the date of First Commercial Sale of such Profit Share Product, any Related Licensed Products. In lieu of any milestone payments that would otherwise be due pursuant to Section 10.5 of the Agreement with respect to any Profit Share Product and Related Licensed Products after First Commercial Sale of such Profit Share Product, Janssen shall pay to Fate milestone payments pursuant to Section 6.2.2 or 6.2.3 of this Exhibit for each Janssen Antigen for which there are one or more Profit Share Products. Section 6.2.2 shall apply if no Related Licensed Product has been sold anywhere in the Territory on the date of First Commercial Sale of the applicable Profit Share Product in the Territory. Otherwise, Section 6.2.3 shall apply.
- 6.2.2 As part of the royalty report delivered pursuant to Section 10.6.5 of the Agreement, Janssen shall notify Fate the first time the Annual Net Sales of the Profit Share Product(s) in the OUS Territory and the Related Licensed Product(s) in the Territory for each applicable Janssen Antigen in a Calendar Year by Janssen, its Affiliates and its Sublicensees exceed, in the aggregate, any of the threshold amounts set forth in the applicable column of the table below (each, a "Profit Share Sales Milestone Event"). Net Sales of a particular Profit Share Product in the OUS Territory, or a particular Related Licensed Product in the Territory, in a particular country occurring after the expiration of the Royalty Term (but during the Term) for such Profit Share Product or such Related Licensed Product in such country shall be included in the calculation of Annual Net Sales for purposes of calculating the amount in the first column of the table below in this Section 6.2.2. For clarity, Net Sales of the Profit Share Product in the U.S. shall be disregarded in the calculation of Net Sales for purposes of this Section 6.2.2. Subject to the remainder of this Section 6.2, Janssen shall pay to Fate the corresponding milestone payment in the table set forth below within [\*\*\*] days after the end of the Calendar Quarter during which such Profit Share Sales Milestone Event is achieved.

Annual Net Sales of the Profit Share Product(s) in the OUS Territory and the	Milestone Payments					
Related Licensed Product(s) in the Territory first exceed:	Janssen Antigen 1	Janssen Antigen 2	Janssen Antigen 3	Janssen Antigen 4		
\$[***]	\$[***]	\$[***]	\$[***]	\$[***]		
\$[***]	\$[***]	\$[***]	\$[***]	\$[***]		
\$[***]	\$[***]	\$[***]	\$[***]	\$[***]		
\$[***]	\$[***]	\$[***]	\$[***]	\$[***]		

- **6.2.3** If a Related Licensed Product has been sold anywhere in the Territory and a Sales Milestone Event has been achieved with respect to such Related Licensed Product on the date of First Commercial Sale of the applicable Profit Share Product, then (a) the table set forth above shall not apply, (b) the Parties will negotiate in good faith and mutually agree on proportionate reductions to the payment amounts set forth in the table above in Section 6.2.2 and (c) the calculation of Annual Net Sales for purposes of such thresholds will aggregate the Annual Net Sales of the Profit Share Product in the OUS Territory and the Annual Net Sales of the Related Licensed Products in the Territory (unless otherwise agreed by the Parties).
- **6.2.4** If there are two or more Profit Share Products, or two or more Related Licensed Products, with respect to the same Janssen Antigen, references in Sections 6.2.2 and 6.2.3 to "Profit Share Product" shall be deemed to refer collectively to such Profit Share Products and to "Related Licensed Product" shall be deemed to refer collectively to such Related Licensed Products.
- **6.2.5** The milestone payments under this Section 6.2 shall be non-refundable and noncreditable. [\*\*\*] The Annual Net Sales of the Profit Share Product in the OUS Territory and the Annual Net Sales of the Related Licensed Products in the Territory shall be aggregated together in the calculation of Annual Net Sales for purposes of this Section 6.2. For clarity, if two or more Profit Share Sales Milestone Events occur in one Calendar Year, then the milestone payments for all such Profit Share Sales Milestone Events shall be payable.

**6.2.6** [\*\*\*].

# 6.3 Shared Development Costs and Shared CMC Development Costs.

- **6.3.1** Cost Sharing. Shared Development Costs and Shared CMC Development Costs incurred during the Profit Share Term for the Profit Share Product by the Parties and their Affiliates shall be borne [\*\*\*] percent ([\*\*\*]%) by Janssen and [\*\*\*] percent ([\*\*\*]%) by Fate. Neither Shared Development Costs nor Shared CMC Development Costs will be included in Allowable Expenses for purposes of calculating U.S. Pre-Tax Profits and Losses, and any amounts included in Allowable Expenses will not be included in Shared Development Costs or Shared CMC Development Costs.
- 6.3.2 <u>Development Costs Prior to Opt-In Exercise Date.</u> Within [\*\*\*] days after the Opt-In Exercise Date for the Profit Share Product, Janssen shall provide a final statement of (i) the Development costs incurred by Janssen (excluding any amounts incurred under the Research Plan) to Develop the Profit Share Product in the Territory prior to the Opt-In Exercise Date, where such costs would otherwise qualify as Shared Development Costs for such Profit Share Product and (ii) the CMC Development Costs incurred by Janssen (excluding any amounts incurred under the Research Plan), or incurred by Fate and reimbursed by Janssen under Section 10.7 of the Agreement, for the Profit Share Product in the Territory prior to the Opt-In Exercise Date where such costs would otherwise qualify as Shared CMC Development Costs (collectively, the "Janssen Development Costs"). Fate shall reimburse Janssen for [\*\*\*] percent ([\*\*\*]%) of all Janssen Development Costs by [\*\*\*].

### **6.3.3** Cost Reports.

- (a) Shared Development Costs and Shared CMC Development Costs shall initially be borne by the Party incurring the cost or expense, subject to reimbursement as provided in Section 6.3.4 of this Exhibit. Each Party shall calculate and maintain records of Shared Development Costs and Shared CMC Development Costs incurred by it and its Affiliates in accordance with procedures to be established by the JFC in coordination with the JDC.
- **(b)** The procedures for quarterly reporting of actual results, quarterly review and discussion of potential discrepancies, quarterly reconciliation, reasonable cost forecasting, and other finance and accounting matters related to Shared Development Costs and Shared CMC Development Costs will be determined by the JFC (the "**Development Reconciliation Procedures**"). Such procedures will provide the ability to comply with financial reporting requirements of each Party.
- (c) The Development Reconciliation Procedures will provide that, within [\*\*\*] days after the end of each Calendar Quarter, each Party shall submit to the JFC a report, in a format established by the JFC, of all Shared Development Costs and Shared CMC Development Costs incurred by such Party and its Affiliates during such Calendar Quarter (each, a "Cost Report"). Within [\*\*\*] days following the receipt of each Cost Report, each Party shall have the right to request reasonable additional information (as determined by the JFC) related to the other Party's and its Affiliates' Shared Development Costs and Shared CMC Development Costs during such Calendar Quarter in order to confirm that such other Party's spending is in conformance with the approved Development Budget or CMC Development Budget, as applicable.

(d) The JFC shall establish reasonable procedures for the Parties to share estimated Shared Development Costs and Shared CMC Development Costs for each Calendar Quarter before the end of such Calendar Quarter, to enable each Party to appropriately accrue its share of Shared Development Costs and Shared CMC Development Costs for financial reporting purposes.

# **6.3.4** Reimbursement of Shared Development Costs and Shared CMC Development Costs.

- Development Costs and Shared CMC Development Costs with respect to a Calendar Quarter shall be paid by the other Party an amount of cash sufficient to reconcile to its agreed percentage of actual Shared Development Costs and Shared CMC Development Costs in such Calendar Quarter pursuant to Section 6.3.1 of this Exhibit. Notwithstanding the foregoing, on a Calendar Year-to-date basis, the Parties shall not share any Shared Development Costs in excess of the amounts allocated for such Calendar Year-to-date period in the Development Budget, or any Shared CMC Development Costs in excess of the amounts allocated for such Calendar Year-to-date period in the CMC Development Budget, except as follows:
  - (i) Shared Development Costs in excess of the Development Budget, and Shared CMC Development Costs in excess of the CMC Development Budget, shall be included in the calculation of Shared Development Costs or Shared CMC Development Costs, as applicable, to be shared by the Parties to the extent such excess Shared Development Costs or Shared CMC Development Costs, as applicable, do not exceed [\*\*\*] percent ([\*\*\*\*]%) of the total Shared Development Costs or Shared CMC Development Costs, as applicable, allocated to be incurred by such Party and its Affiliates in the applicable Calendar Year-to-date period in accordance with the Development Budget or CMC Development Budget, as applicable, for such Calendar Year; and
  - (ii) the Parties shall share any and all Shared Development Costs in excess of the Development Budget, and any and all Shared CMC Development Costs in excess of the CMC Development Budget, to the extent attributable to: [\*\*\*].
- If any excess Shared Development Costs or Shared CMC Development Costs are (b) excluded from sharing by the Parties for a particular Calendar Year-to-date period pursuant to Section 6.3.4(a) of this Exhibit, such excess Shared Development Costs or Shared CMC Development Costs shall be carried forward to the subsequent Calendar Quarters (provided that such Calendar Quarters fall within the same Calendar Year) and, to the extent the total Shared Development Costs or Shared CMC Development Costs incurred by such Party and its Affiliates for the Calendar Year-to-date as of the end of such subsequent Calendar Quarter are less than [\*\*\*] percent ([\*\*\*]%) of the aggregate Shared Development Costs or Shared CMC Development Costs allocated to such Party under the Development Budget or CMC Development Budget, as applicable, for such Calendar Year-to-date period, such carried forward amounts shall be included in Shared Development Costs or Shared CMC Development Costs, as applicable, to be shared by the Parties for such Calendar Year-to-date-period (i.e., so that the total Shared Development Costs or Shared CMC Development Costs, as applicable, incurred by such Party and its Affiliates that are shared pursuant to this Section during any Calendar Year do not exceed [\*\*\*] percent ([\*\*\*]%) of the Shared Development Costs or Shared CMC Development Costs, as applicable, allocated to such Party under the Development Budget or CMC Development Budget, as applicable for such Calendar Year, unless otherwise approved by the JSC). For clarity, at the end of the Calendar Year, any amounts in excess of [\*\*\*] percent ([\*\*\*]%) of the aggregate Shared Development Costs allocated to such Party under the Development Budget, or in excess of [\*\*\*] percent ([\*\*\*]%) of the aggregate Shared CMC Development Costs allocated to such Party under the CMC Development Budget, for such Calendar Year shall be borne solely by such Party and shall not be shared by the other Party.

(c)	The Development Reconcil	iation Procedures shall r	equire the JFC to develo	op a written
report setting out the calculation	of any net amount owed by Fat	e to Janssen or by Janss	sen to Fate, as the case	may be, as
necessary to accomplish the sharin	g of Shared Development Costs a	and Shared CMC Develop	pment Costs set forth in t	his Section,
and to prepare such report promp	otly following delivery of the C	ost Reports and in a rea	asonable time (to be det	fined in the
<b>Development Reconciliation Proce</b>	dures) in advance of payment.			
_				

- (d) The net amount payable to accomplish the sharing of Shared Development Costs and Shared CMC Development Costs as provided under this Exhibit shall be paid by Janssen or Fate, as the case may be, within [\*\*\*] days after the end of the applicable Calendar Quarter.
- **(e)** In establishing the Development Reconciliation Procedures, the JFC shall work to coordinate and harmonize the Development Reconciliation Procedures with the U.S. Reconciliation Procedures to permit for reconciliation, and associated payments, with respect to Shared Development Costs, Shared CMC Development Costs and U.S. Pre-Tax Profits and Losses within [\*\*\*] days after the end of the applicable Calendar Quarter.

### 6.4 U.S. Pre-Tax Profits and Losses.

**6.4.1** <u>U.S. Pre-Tax Profits and Losses</u>. In partial consideration for the licenses granted by Fate to Janssen in accordance with Section 5.1.2 of the Agreement with respect to the Profit Share Product, the Parties shall share in U.S. Pre-Tax Profits and Losses as follows: Fate shall bear (and be entitled to) [\*\*\*]%, and Janssen shall bear (and be entitled to) [\*\*\*]%. The U.S. Pre-Tax Profits and Losses shall be calculated as set forth in the Financial Exhibit.

#### **6.4.2** Quarterly Reconciliation and Payments.

- (a) Procedures for quarterly reporting of actual results and review and discussion of potential discrepancies, quarterly reconciliation, reasonable forecasting, and other finance and accounting matters, to the extent not set forth in the Financial Exhibit, will be established by the JFC (the "U.S. Reconciliation Procedures"). Such procedures will provide the ability to comply with financial reporting requirements of each Party.
- (b) The U.S. Reconciliation Procedures shall provide that within [\*\*\*] days after the end of each Calendar Quarter, each Party shall submit to the JFC a report, in such reasonable detail and format as is established by the JFC, of all amounts necessary to calculate U.S. Pre-Tax Profits and Losses including Net Sales, Other Income and Allowable Expenses. Within [\*\*\*] days following the receipt of such report, each Party shall have the right to request reasonable additional information (as determined by the JFC) necessary to permit calculation and reconciliation of U.S. Pre-Tax Profits and Losses for the applicable Calendar Quarter, including to confirm that Allowable Expenses are in conformance with the approved U.S. Commercialization Budget.

(c) The U.S. Reconciliation Procedures shall provide for the JFC to develop a written report setting
forth the calculation of U.S. Pre-Tax Profits and Losses for the applicable Calendar Quarter, amounts owed by Fate to Janssen or
by Janssen to Fate, as the case may be, as necessary to accomplish the sharing of U.S. Pre-Tax Profits and Losses for the
applicable Calendar Quarter, and to prepare such report promptly following delivery of the reports from the Parties as described
above in this Section and in a reasonable time (to be defined in the U.S. Reconciliation Procedures) in advance of applicable
payments to accomplish the sharing of U.S. Pre-Tax Profits and Losses for the applicable Calendar Quarter.

- (d) Payments to reconcile U.S. Pre-Tax Profits and Losses shall be paid within [\*\*\*] days after the end of each Calendar Quarter.
- (e) The JFC shall establish reasonable procedures for the Parties to share estimated Allowable Expenses, Net Sales and Other Income for each Calendar Quarter before the end of such Calendar Quarter, to enable each Party to appropriately accrue its share of U.S. Pre-Tax Profits and Losses for financial reporting purposes.

# 6.5 Royalties.

- **6.5.1** Section 10.6.1 of the Agreement shall not apply to any Profit Share Product, but will apply to any Related Licensed Products. In lieu of any royalties that would otherwise be due with respect to any Profit Share Products pursuant to Section 10.6.1 of the Agreement, Janssen shall pay to Fate royalties pursuant to Section 6.5.2 of this Exhibit.
- **6.5.2** Subject to the remainder of this Section 6.5, in partial consideration of the licenses granted by Fate to Janssen in accordance with Section 5.1.2 of the Agreement, Janssen shall pay to Fate royalties at a rate of [\*\*\*] percent ([\*\*\*]%) on the aggregate Annual Net Sales of each Profit Share Product during the applicable Royalty Term by Janssen, its Affiliates and Sublicensees in the OUS Territory.
- **6.5.3** If there are two or more Profit Share Products with respect to the same Janssen Antigen, references in Section 6.5.2 to "Profit Share Product" shall be deemed to refer collectively to such Profit Share Products.
- **6.5.4** The provisions of Sections 10.6.2, 10.6.3 and 10.6.5 of the Agreement shall apply to the payments under this Section 6.5 *mutatis mutandis*. Janssen may in its discretion deliver a single report pursuant to Section 10.6.5 of the Agreement with respect to royalties payable under Section 10.6 of the Agreement and this Section 6.5.
- **6.6 Payment Terms**. Sections 10.9, 10.10, 10.11 and 10.12 of the Agreement shall apply with respect to payments under this Article VI.

#### ARTICLE VII TRADEMARKS

- **7.1 Trademarks**. Section 5.7.1 of the Agreement shall not apply with respect to any Profit Share Product. In addition to the other provisions of the Agreement (and in lieu of Section 5.7.1 of the Agreement), the following terms of this Article VII shall apply to the Product Trademarks relating to the Profit Share Products during the Profit Share Terms.
- 7.1.1 Product Trademarks. Janssen will manage the development and clearance process for proposed names for Product Trademarks for Profit Share Products, including the hiring of appropriate Subcontractors and conducting development activities, name safety testing, market research and legal searches. [\*\*\*] percent ([\*\*\*]%) of the costs of the development and searching/clearance process of such proposed Product Trademarks shall be included as Allowable Expenses. Janssen shall select all Product Trademarks for the Profit Share Product, and Janssen will own all right, title and interest in and to the Product Trademarks for the Profit Share Product. Neither Party will, and will ensure that its Affiliates do not: (i) challenge any Product Trademark or the registration thereof in any country (other than based upon a trademark filed or used by Fate or Janssen prior to knowledge of the Product Trademark); (ii) file, register or maintain any registrations for any trademarks or trade names that are confusingly similar to any Product Trademark (other than for the Profit Share Product), in any country without the express prior written consent of the other Party; or (iii) authorize or assist any Third Party to do the foregoing. Janssen shall also be responsible for registering and maintaining all Product Domain Names and Websites for the Profit Share Product and shall own all rights, title and interest in such Product Domain Names and Websites.
- 7.1.2 Prosecution and Maintenance. Janssen shall be responsible for prosecution and maintenance of all Product Trademarks pertaining to the Profit Share Products and for registering and maintaining all Product Domain Names and Websites for Profit Share Products. If Janssen determines, in its sole discretion, to abandon or not maintain any such Product Trademark in the U.S., then Janssen shall provide Fate with written notice of such determination within a period of time sufficiently in advance to enable Fate to determine whether it will assume responsibility for such Product Trademark (which notice shall be given no later than [\*\*\*] days prior to any final deadline for any pending action or response that may be due with respect to such Product Trademark with the applicable trademark authority). If Fate provides written notice to Janssen that it will assume responsibility for such Product Trademark in the U.S., Janssen shall transfer such responsibility to Fate and shall execute any documents necessary to complete such transfer. The Out-of-Pocket Expenses of prosecution and maintenance of Product Trademarks pertaining to the Profit Share Products, and registration and maintenance of Product Domain Names and Websites for Profit Share Products, in the U.S. shall be included as Allowable Expenses.
- 7.1.3 Coordination Regarding Product Trademarks. The JSC shall discuss and agree on an overall strategy pertaining to the Product Trademarks pertaining to the Profit Share Products and related marks and activities, however [\*\*\*] shall have the [\*\*\*] regarding selection of the Product Trademarks for the Profit Share Products. Janssen will provide updates to the JSC as reasonably requested by Fate regarding filing and material issues pertaining to such Product Trademarks. Each Party may use the Product Trademarks solely to carry out its respective obligations under this Exhibit.

#### 7.1.4 <u>Housemark Licenses</u>.

- (a) *To Janssen*. Fate hereby grants to Janssen a non-exclusive, royalty-free license to use the Fate Housemarks solely as set forth in the promotional materials for the Profit Share Products and other materials provided to it by Fate, and solely to Develop and Commercialize the Profit Share Products in accordance with this Exhibit.
- **(b)** *To Fate.* Janssen hereby grants to Fate a non-exclusive, royalty-free license to use the Janssen Housemarks and Product Trademarks solely as set forth in the promotional materials for the Profit Share Products and other materials provided to it by Janssen, and solely to Commercialize the Profit Share Products in accordance with this Exhibit.
- (c) Rights in Housemarks. Janssen will not have, assert or acquire any right, title or interest in or to any Fate Housemarks or the goodwill pertaining thereto, and Fate will not have, assert or acquire any right, title or interest in or to any Janssen Housemarks or the goodwill pertaining thereto, in each case by means of entering into or performing under the Agreement or this Exhibit, except in each case for the limited licenses explicitly provided in the Agreement or this Exhibit. All use by a Party of the Housemarks of the other Party shall inure to the benefit of such other Party.
- **7.1.5** Required Use and Compliance. Each Party agrees that it and its Affiliates will: (i) ensure that each use of the Product Trademarks and the other Party's Housemarks by such Party is accompanied by an acknowledgement that the Product Trademarks or Housemarks are owned by the other Party (i.e. the use by one Party of the other Party's Housemark shall indicate that such Housemark is used under license) and includes the trademark registration symbol ® or TM as appropriate; (ii) not use the Product Trademarks or the other Party's Housemarks in a way that might materially prejudice their distinctiveness or validity or the goodwill of the other Party therein; and (iii) not use any trademarks or trade names so resembling any of the Product Trademarks or the other Party's Housemarks as to be likely to cause confusion or deception; and (iv) use the other Party's Housemarks in accordance with that Party's reasonable quality standards as notified in writing from time to time. Each Party may use the other Party's Housemarks solely to carry out its respective obligations under this Exhibit.

### 7.1.6 <u>Trademark Infringement.</u>

Each Party will monitor the Product Trademarks pertaining to the Profit Share Products in the U.S. and Janssen will monitor such Product Trademarks in the OUS Territory against infringing uses relating to the Profit Share Products. Each Party will promptly notify the other Party of any infringement or threatened infringement of any of such Product Trademarks of which it becomes aware. Each Party may use Third Party watch services, as necessary, to monitor filings for similar Third Party trademarks. Except to the extent that Fate has assumed responsibility for a Product Trademark pertaining to any Profit Share Product in the U.S. in accordance with Section 7.1.2, Janssen shall defend the Product Trademarks pertaining to the Profit Share Products in the U.S. and OUS Territory against oppositions, nullity or other legal actions filed by Third Parties and shall promptly undertake to oppose, nullify or take other appropriate action, where reasonable, against similar or identical Third Party trademarks filed for products or services related to those claimed by such Product Trademarks. Janssen will determine what action, if any, to take in response to any such opposition, infringement or threatened infringement of any such Product Trademark in accordance with this Section 7.1.6.

- Janssen shall be primarily responsible for protecting and maintaining the Product (b) Trademarks pertaining to the Profit Share Products, including all enforcement and defense thereof. Fate may, at its own expense with respect to actions in the OUS Territory, participate in any litigation relating to the enforcement or defense of any such Product Trademark in a subordinate role and Janssen shall consider input on strategy and tactics offered by Fate. In the event Janssen fails to initiate a suit or take other commercially reasonable action to enforce or defend any such Product Trademark in the U.S. within [\*\*\*] days after becoming aware of the basis for such suit or actions, then Fate may, in its discretion, provide Janssen with notice of its intent to initiate a suit or take other commercially reasonable action with respect to the enforcement and defense of such Product Trademark. If Fate provides such notice and Janssen fails to initiate a suit or take such other commercially reasonable action within [\*\*\*] days after receipt of such notice from Fate, then Fate shall have the right to initiate a suit or take other commercially reasonable actions that it believes are reasonably required to enforce and defend such Product Trademark in the U.S. The non-enforcing Party may participate in any such action and be represented in any such action by its own counsel and the enforcing Party shall consider the input on strategy and tactics offered by the non-enforcing Party. The nonenforcing Party shall, at the enforcing Party's expense, provide all assistance reasonably requested by the enforcing Party in connection with the maintenance, enforcement and defense of the applicable Product Trademarks. Each Party will be responsible for all expenses it incurs under this Section 7.1.6 for the OUS Territory, and all Out-of-Pocket Expenses incurred under this Section 7.1.6 with respect to the U.S. will be included in Allowable Expenses.
- 7.1.7 Recording of License. If Fate considers it advisable to record Fate as a licensee or "registered user" of any of the Product Trademarks pertaining to any Profit Share Product under local law, Janssen shall do all such acts and sign or have signed all such documents as are reasonably proper and necessary to secure such recordation and for any changes thereof in the future. In such event, Fate shall be responsible for recording the Agreement or this Exhibit, or a document reflecting the contents of the Agreement or this Exhibit, with any applicable Governmental Authority, and all associated recordation fees and related costs and expenses shall be included in Allowable Expenses. Upon termination of Fate's right to use a Product Trademark, Janssen may at any time thereafter apply for cancellation of the record of Fate as a licensee upon written notice to Fate, and Fate consents to such cancellation.

# ARTICLE VIII PRODUCT LIABILITY CLAIMS

- 8.1 Product Liability Claims.
- **8.1.1** "**Product Liability Costs**" means amounts paid to Third Parties (including damages and amounts paid in settlement to Third Parties and reasonable attorneys' and experts fees and expenses), and internal costs incurred, by the Parties and their Affiliates that are associated with [\*\*\*].
  - **8.1.2** "**Shared Product Liability Costs**" means all Product Liability Costs other than [\*\*\*].

- **8.1.3** All Shared Product Liability Costs shall be borne [\*\*\*]% by Janssen and [\*\*\*]% by Fate. Product Liability Costs that are Losses entitled to indemnification under [\*\*\*] shall be borne by the Indemnitor. Product Liability Costs that relate to [\*\*\*].
- 8.1.4 Each of the Parties shall promptly notify the other in the event that any Third Party asserts or files any products liability claim or other claim, suit, proceeding, litigation or action relating to alleged defects in the Profit Share Product (whether design defects, manufacturing defects or defects in sales or marketing) ("Third Party Products Liability Action") against such Party; provided, however, failure to give or delay in giving such notice shall not relieve either Party of its obligations under this Section 8.1, except to the extent the other Party is actually, materially prejudiced as a result of such failure or delay. To the extent such Third Party Products Liability Action relates to the Commercialization of the Profit Share Product in the OUS Territory, Janssen shall have the sole right to defend and settle such Third Party Products Liability Action at its sole expense. With respect to any other Third Party Products Liability Action (a "Shared Third Party Products Liability Action"), Janssen shall have the first right to defend and settle such Shared Third Party Products Liability Action. In the event that Janssen does not assume the defense of such Shared Third Party Products Liability Action within [\*\*\*] days following delivery and receipt of notice described in the first sentence of this Section 8.1.4. Fate may notify Janssen of Fate's desire to take the lead role in the defense of such Shared Third Party Products Liability Action. If, within [\*\*\*] days after Fate notifies Janssen of such desire, Janssen does not assume defense of such Shared Third Party Products Liability Action, then Fate may take the lead role in the defense of such Shared Third Party Products Liability Action. Each Party agrees to cooperate and to provide reasonable assistance to the other Party with respect to any Third Party Products Liability Action.
- **8.1.5** The Party assuming the defense of any Shared Third Party Products Liability Action under this Section 8.1 (the "Controlling Party") shall consult with the other Party on all material aspects of the defense, including settlement, of such Shared Third Party Products Liability Action, and the Parties shall cooperate fully with each other in connection therewith. The non-defending Party shall also have the right to participate in the defense of any Shared Third Party Products Liability Action utilizing attorneys of its choice, and any expenses incurred in connection with such participation (including reasonable attorney's fees) will be included in Shared Product Liability Costs and allocated between the Parties in accordance with Section 8.1.3. In furtherance of the Parties' cooperation, the Controlling Party will consult with the other Party regarding strategic decisions, including the retention of counsel and defense of each Shared Third Party Products Liability Action. The Controlling Party will otherwise keep the other Party fully informed of the status and progress of the defense and any settlement discussions concerning the Shared Third Party Products Liability Action. Any settlement of a Shared Third Party Products Liability Action that would admit liability on the part of any Party or its Affiliates, or that would involve any relief other than the payment of money damages within a budget previously agreed to by the Parties, shall be subject to the prior written approval of both Parties, such approval not to be unreasonably withheld, delayed or conditioned. All damages and expenses (including reasonable attorney's fees of the Controlling Party) incurred in connection with the defense of a Third Party Products Liability Action shall be allocated between Janssen and Fate in accordance with Section 8.1.3.

**8.1.6** Shared Product Liability Costs shall initially be borne by the Party incurring the cost or expense, subject to quarterly reimbursement (or such other reimbursement schedule as the JFC may approve) pursuant to procedures to be established by the JFC. Each Party shall calculate and maintain records of Shared Product Liability Costs incurred by it and its Affiliates in accordance with procedures to be established by the JFC promptly following commencement of any Shared Third Party Products Liability Action.

# ARTICLE IX TERMINATION

### 9.1 Effects of Termination.

9.1.1

(a) If Janssen terminates the Agreement in its entirety, or with respect to a Janssen Antigen targeted by a Profit Share Product, under Section 15.3 of the Agreement (Janssen Unilateral Termination Rights), or if Fate terminates the Agreement under Section 15.2 (Termination for Material Breach) or Section 15.5 (Termination for Insolvency), then Fate will have a right to elect to continue developing, manufacturing and commercializing any applicable Reverted Profit Share Product by giving notice to Janssen at least [\*\*\*] days before the effective date of termination. For purposes of this Exhibit, a "Reverted Profit Share Product" means [\*\*\*].

If Fate makes such election, Janssen hereby grants to Fate, effective as of the effective date of termination, a perpetual, worldwide, exclusive, royalty-bearing, irrevocable license with a right to sublicense (in multiple tiers) under Patents and Know-How Controlled by Janssen or its Affiliates to the extent reasonably necessary for Fate to Develop, have Developed and use, to make, have made and otherwise Manufacture, and to sell, have sold, offer for sale, import and otherwise Commercialize the Reverted Profit Share Product (including, in each case, its Master iPSC Bank and CD34 Composition) in the Field in the Territory; provided, however, that: (i) if any such Patent or Know-How was in-licensed or acquired from a Third Party and is subject to payment or other obligations to such Third Party, Janssen shall promptly disclose such obligations to Fate in writing and such Patent or Know-How shall be subject to the license granted in this Section only to the extent (x) if applicable, such Third Party consents to the sublicensing of such Patent or Know-How to Fate and (y) Fate agrees in writing to be bound by such obligations and reimburse all amounts owed to such Third Party as a result of Fate's exercise of such license with respect to such Patent or Know-How; (ii) the Patents licensed to Fate pursuant to this Section shall not include any proprietary manufacturing, formulation or drug delivery technology of Janssen that was not actually used by or on behalf of Janssen in the Development, Manufacture, or Commercialization of the Reverted Profit Share Product; and (iii) the Know-How licensed to Fate shall not include any Confidential Information of Janssen relating to the Commercialization of Janssen oncology products generally that is disclosed pursuant to Article V of this Exhibit and is marked by Janssen as "Competitively Sensitive Information" in accordance with Section 5.4.1 of the Agreement.

	(c)	If Fate does not	elect to conti	nue developing	and comme	ercializing th	ne Reverted Profit
Share Product in a	ccordance with	this Section, then	Janssen shall	wind down all	of its De	velopment,	Manufacture, and
Commercialization a	activities with res	spect to the Profit S	hare Product a	s quickly as reas	sonably prac	cticable, sub	ject to compliance
with ethical and leg with the terms of thi				share the reasona	able costs o	f such activi	ties in accordance

- **9.1.2** If Fate elects to continue developing and commercializing the Reverted Profit Share Product in accordance with Section **9.1.1** of this Exhibit, the following provisions of this Section 9.1.2 shall apply upon the effective date of such termination solely with respect to the Reverted Profit Share Product:
- (a) If there are any Patents or Know-How licensed under Section 9.1.1(b) and Fate practices such license in connection with its development and commercialization of the Reverted Profit Share Product, then Fate shall pay to Janssen royalties at a rate equal to [\*\*\*] ([\*\*\*]%) of the royalty rates set forth in Section 10.6 of the Agreement; otherwise, Fate shall pay to Janssen royalties at a rate equal to [\*\*\*] ([\*\*\*]%) of the royalty rates set forth in Section 10.6 of the Agreement. Such payments shall be on the same terms set forth in Section 10.6 of the Agreement with respect to Net Sales of Licensed Products *mutatis mutandis*, *provided* that the definition of Royalty Term in Section 10.6.2 of the Agreement shall remain the same.
- (b) As soon as practicable, Janssen will assign or otherwise transfer to Fate all Regulatory Filings and Regulatory Approvals (which, for clarity, shall exclude any Regulatory Filings or Regulatory Approvals for, or any portion thereof pertaining to, any compound or product that is not the Reverted Profit Share Product) and copies of all clinical and nonclinical data relating to the Reverted Profit Share Product Controlled by Janssen or any of its Affiliates or Sublicensees. Janssen shall, and shall procure that its Affiliates and Sublicensees shall, take such actions and execute such instruments, assignments and documents as may be reasonably requested by Fate to effect the transfer of rights under such Regulatory Filings and Regulatory Approvals to Fate. If applicable Law prevents or delays the transfer of ownership of any such Regulatory Filings or Regulatory Approvals to Fate, Janssen shall grant, and does hereby grant, to Fate an exclusive and irrevocable right of access and reference to such Regulatory Filings and Regulatory Approvals for the Reverted Profit Share Product, and shall cooperate with Fate to make the benefits of such Regulatory Filings and Regulatory Approvals available to Fate or its designee(s) with effect from the effective date of such termination.
- **(c)** If Janssen is Manufacturing the Reverted Profit Share Product, Janssen hereby grants Fate (effective upon the effective date of such termination) a right of reference to any DMF or master files within the possession and Control of Janssen or its Affiliates that are necessary for the Manufacture of the Reverted Profit Share Product.
- **(d)** Following receipt of written request from Fate, Janssen shall deliver to Fate all safety data contained in the global safety database for the Reverted Profit Share Product and promptly transfer control of and responsibility for maintaining the global safety database for the Reverted Profit Share Product to Fate.

(e) If Janssen is, as of the effective date of termination of the Agreement, party to any subcontracts or Sublicenses that pertain solely to the Reverted Profit Share Product, then Janssen will assign to Fate any such subcontracts or Sublicenses requested by Fate, to the extent it has the right under such contract(s) to do so (and will use reasonable efforts to obtain any required consents). If Janssen is not able to assign any such subcontracts or Sublicenses, at Fate's request, or in the event that any subcontract pertains both to the Reverted Profit Share Product and to any other product of Janssen, Janssen shall use [\*\*\*] Efforts to facilitate negotiations between Fate and any of Janssen's Subcontractors or Sublicensees that at the effective date of termination are performing any Development, Manufacturing or Commercialization activities with respect to the Reverted Profit Share Product, subject to Fate's agreement to any associated reasonable costs.

Janssen shall transfer to Fate, at Fate's request, any remaining inventory of the Reverted Profit Share Product, and components thereof and raw materials used by or on behalf of Janssen in the Manufacture of the Reverted Profit Share Product (collectively, "Inventory"), that, in each case, is in Janssen's or its Affiliate's possession as of the effective date of termination at a price equal to [\*\*\*]; provided, however, that to the extent any Inventory in Janssen's possession as of the effective date of termination is necessary for Janssen to perform its supply obligations under Section 9.1.2(g) or its Commercialization Wind-Down Period obligations under Section 9.1.2(i) (if any) after the effective date of termination, then Janssen's Inventory transfer obligations under the preceding provisions of this Section shall apply to any Inventory that is in Janssen's possession as of the date Janssen's obligations under Section 9.1.2(g) or Section 9.1.2(i) (as applicable) expire or terminate (or, if earlier, as of the date that Janssen no longer requires such Inventory for the performance of such obligations). Within [\*\*\*] days after the effective date of termination (or within [\*\*\*] days after such later date described in the preceding proviso, if applicable), Janssen shall notify Fate (i) of the quantity(ies) and type(s) of the remaining Inventory and the Cost of Goods thereof and (ii) whether any such Inventory will need to be relabeled or repackaged to remove any Janssen Housemarks, and Fate shall have [\*\*\*] days after receipt of such notice in which to notify Janssen of the quantity(ies) and type(s) of the remaining Inventory that Fate wishes to acquire. If Fate does not so notify Janssen within the applicable period specified above, or notifies Janssen within the applicable period specified above that Fate elects to purchase less than all of the remaining Inventory, then (i) in the case of Inventory remaining in Janssen's possession as of the effective date of termination, Janssen shall be entitled to elect to continue to sell such Inventory for up to [\*\*\*] after the effective date of termination, or to destroy such Inventory, and (ii) in the case of Inventory remaining in Janssen's possession as of the date Janssen's obligations under Section 9.1.2(g) or Section 9.1.2(i) (as applicable) expire or terminate (or, if earlier, as of the date that Janssen no longer requires such Inventory for the performance of such obligations), Janssen shall destroy such Inventory. Any Reverted Profit Share Product that is Commercialized by Janssen after the effective date of termination pursuant to this Section (x) in the OUS Territory, shall be subject to payment of royalties pursuant to Section 6.5 of this Exhibit, and (y) in the U.S., shall be subject to Section 6.4 of this Exhibit.

(g	<b>)</b> Janssen shall	, at Fate's request,	use [***] Effort	ts to facilitate an orde	erly and prompt
transition of any Manufacturing	of the Reverted Profi	t Share Product then	being conducted	l by Janssen and any of	its Affiliates or
Third Party subcontractors to 1	Fate or its designee.	At Fate's request,	while such Mai	nufacturing activities	are transitioned,
Janssen shall supply Fate or its	designee with the R	everted Profit Share	e Product at a pr	rice equivalent to [***	], provided that
Janssen shall not be obligated to	continue to supply th	e Reverted Profit Sh	nare Product for r	more than [***] follow	ing the effective
date of termination.					J

- **(h)** Janssen shall return to Fate all Master iPSC Banks and CD34 Compositions for the Reverted Profit Share Product in Janssen's possession, and Janssen shall assign, and hereby assigns to Fate, effective upon the effective date of termination, title to all Master iPSC Banks for the Reverted Profit Share Product.
- (i) If the First Commercial Sale of the Reverted Profit Share Product has occurred in a country prior to the effective date of termination of the Agreement, then, if requested by Fate, Janssen shall continue to Commercialize the Reverted Profit Share Product in such country in accordance with the terms and conditions of the Agreement, for a period requested by Fate not to exceed [\*\*\*] from the effective date of termination of the Agreement (the "Commercialization Wind-Down Period"), provided that Fate may terminate such activities during the Commercialization Wind-Down Period upon [\*\*\*] days' notice to Janssen. Any Reverted Profit Share Product Commercialized by Janssen during the Commercialization Wind-Down Period (x) in the OUS Territory, shall be subject to payment of royalties pursuant to Section 6.5 of this Exhibit, and (y) in the U.S., shall be subject to Section 6.4.
- (j) To the extent permitted by applicable Law, Janssen shall transfer to Fate promotional materials, sales training materials, Commercialization plans and customer contact information in Janssen's possession that are solely related to Commercialization of the Reverted Profit Share Product (subject to the transition plan agreed to by the Parties pursuant to Section 9.1.2(n) of this Exhibit with respect to OUS Territory plans and information).
- **(k)** If, at the date of notice of termination, any Clinical Trial is on-going (i.e. first patient dosed prior to the date of notice of termination) with respect to the Reverted Profit Share Product pursuant to the GDP, then Fate shall notify Janssen in writing within [\*\*\*] days after the notice of termination to confirm whether Fate elects to have Janssen:
  - (i) wind down such Clinical Trial as soon as practicable, subject to compliance with ethical and legal requirements; or
  - (ii) transfer responsibility for and control of such Clinical Trial to Fate as soon as practicable. Janssen shall use [\*\*\*] Efforts to effect such transfer, and Fate shall use [\*\*\*] Efforts to assume responsibility for and control of such Clinical Trial as promptly as practicable after the effective date of termination and, in any event, within [\*\*\*] months following the effective date of termination.

The costs of any such Clinical Trial shall be shared by the Parties as Shared Development Costs pursuant to the Agreement or this Exhibit until the effective date of termination, beyond which (1) Shared Development Costs which are incurred in the winding down of any Clinical Trial shall be shared by the Parties in accordance with Section 6.3 of this Exhibit and (2) Shared Development Costs incurred in the conduct of any Clinical Trial that Fate elects to have transferred to Fate shall be borne solely by Fate. If Fate fails to notify Janssen which option ((i) or (ii)) it chooses within the prescribed time period set out in this Section, then Janssen may proceed on the basis that any Clinical Trial should be wound down in accordance with clause (i) of this Section.

- (I) Following the date of notice of termination, Janssen shall have no obligation to initiate any Clinical Trial, or to commence any other new Development activities for the Reverted Profit Share Product. If Fate elects to initiate any Clinical Trial of the Reverted Profit Share Product or to commence any other new Development activities for the Reverted Profit Share Product after the date of notice of termination, then the costs of such activity shall be borne solely by Fate and shall not be shared by the Parties pursuant to Section 6.3 of this Exhibit.
- **(m)** Janssen shall cause to be assigned to Fate all worldwide rights in and to any Product Trademarks and Product Domain Names and Websites solely relating to the Reverted Profit Share Product.
- (n) As soon as practicable following the date of notice of termination, the Parties shall meet to discuss a transition plan that sets forth the steps and process to be followed following the date of notice of termination to achieve an efficient and orderly handover of Development, Manufacturing and Commercialization activities with respect to the Reverted Profit Share Product and to undertake the activities as set out in this Section 9.1.2. Such transition plan will include, at Janssen's election, either a transfer of the existing OUS Territory Commercialization plans and customer contact information with respect to the Reverted Profit Share Product or a process by which the Parties will work together in good faith to develop new OUS Territory Commercialization plans and customer contact information for the Reverted Profit Share Product. Except as expressly provided otherwise in this Section 9.1.2, any costs incurred by the Parties between the date of notice of termination and the effective date of termination to conduct activities pursuant to this Section 9.1.2 shall be shared in accordance with the Agreement or this Exhibit, as applicable, and thereafter each Party shall bear its own costs.
- (o) If, as of the effective date of termination, Janssen is Developing or Commercializing the terminated Profit Share Product as part of a Combination Regimen that includes another drug or biological product that is owned or controlled by Janssen or its Affiliate, then upon Fate's request, the Parties will negotiate in good faith a clinical trial collaboration agreement pursuant to which (i) Janssen would supply such drug or biological product to Fate, solely for Fate's use in conducting one or more clinical trials of the Combination Regimen and (ii) Janssen would provide rights of reference necessary for Fate to seek, obtain and maintain regulatory approval of the Profit Share Product as part of the Combination Regimen.
- **(p)** Fate shall indemnify, defend and hold harmless the Janssen Indemnitees from and against any and all Losses to the extent arising out of or relating to the Research, Development, Commercialization, transfer, Manufacture, handling or storage, or use of, or exposure to, the Reverted Profit Share Product by or for Fate or any of its Affiliates, Sublicensees, agents and contractors, on or after the effective date of termination. Any claim of indemnification by a Janssen Indemnitee under this Section will be subject to the procedures set forth in Section 14.3 of the Agreement.

#### **Exhibit 1.12-1**

#### **Financial Exhibit**

U.S. Pre-Tax Profits and Losses for the Profit Share Product during the Profit Share Term shall be calculated in accordance with this Financial Exhibit.

# (1) <u>Calculation of U.S. Pre-Tax Profits and Losses</u>

**"U.S. Pre-Tax Profits and Losses"** means, for a Calendar Quarter, the amount equal to A + B - C, where A equals the Net Sales of the Profit Share Product in the U.S. for such Calendar Quarter, B equals any Other Income with respect to the Profit Share Product in the U.S. for such Calendar Quarter and C equals the Allowable Expenses incurred with respect to the Profit Share Product in the U.S. for such Calendar Quarter. Any positive U.S. Pre-Tax Profit and Losses may be referred to as a "U.S. Pre-Tax Profit," and any negative U.S. Pre-Tax Profits and Losses may be referred to as a "U.S. Pre-Tax Loss."

U.S. Pre-Tax Profits and Losses shall exclude the upfront payment and all milestone payments, all Shared Development Costs, Shared CMC Development Costs and capital expenditures, and any other cost not specifically included in Allowable Expenses, including costs attributable to general corporate activities, executive management, investor relations, treasury services, business development, corporate government relations, finance, and other corporate overhead. Cost items included in components of U.S. Pre-Tax Profits and Losses shall not be double counted and shall not be included in Shared Development Costs or Shared CMC Development Costs.

Expenses shall not be included in Allowable Expenses for a Calendar Year if such expenses are in excess of the amounts allocated for such Calendar Year in the U.S. Commercialization Budget; except: (a) to the extent such excess expenses do not exceed [\*\*\*] percent ([\*\*\*]%) of the total Allowable Expenses allocated to be incurred by the relevant Party in the Calendar Year in accordance with the latest approved U.S. Commercialization Budget for such Calendar Year; or (b) to the extent attributable to: [\*\*\*].

# (2) <u>Definitions</u>

The following definitions shall apply for purposes of calculating U.S. Pre-Tax Profits and Losses for the Profit Share Product in accordance with this Financial Exhibit.

"Allowable Expenses" means the following Commercial FTE Costs and Out-of-Pocket Expenses incurred by the Parties and their Affiliates in conducting Commercialization activities with respect to the Profit Share Product in the U.S.:

- (a) Allocable Global Costs;
- (b) Charitable Contribution Costs to the extent such costs are directly attributable to a Profit Share Product;
- (c) Collaboration Losses;

- (d) Distribution Costs; (e) Health Care Reform Fees; (f) Marketing Expenses; Medical Affairs Expenses; (g) (h) Other Commercialization Costs; (i) Recall Expenses; Regulatory Maintenance Costs; (i) Selling Costs; (k) (1) Supply Costs; Project Management, Alliance Management and Healthcare Compliance (HCC) Costs; (m)
- (n) Costs described in Sections 7.1.1, 7.1.2, 7.1.6(b) and 7.1.7 as included in Allowable Expenses; and
  - (0) [\*\*\*].

Allowable Expenses that are incurred with respect to both the U.S. and OUS Territory (and that cannot be attributed solely to the U.S. or solely to the OUS Territory) will be allocated [\*\*\*] percent ([\*\*\*]%) to the U.S. and [\*\*\*] percent ([\*\*\*]%) to the OUS Territory, unless otherwise agreed by the Parties (and only the amounts allocated to the U.S. will be included in Allowable Expenses).

To the extent that any activity is conducted (or any Commercial FTE Costs or Out-of-Pocket Expense incurred) in support of both the Profit Share Product and other products, services or efforts of a Party or its Affiliates, including with respect to any product (including any Related Licensed Product) included in a Combination Product or Combination Regimen containing a Profit Share Product, then the Commercial FTE Costs and Out-of-Pocket Expenses thereof shall be included in Allowable Expenses only to the extent allocable to the Profit Share Product and included in the U.S. Commercialization Budget, or expressly and specifically included under this Financial Exhibit (e.g., in the case of Commercial FTE Costs for sales representatives promoting both the Profit Share Product and other products, as specified below). In connection with the JSC's review of a proposed U.S. Commercialization Budget for approval, upon request by either Party, the JSC shall review the methodology used to allocate to Allowable Expenses the Commercial FTE Costs and Out-of-Pocket Expenses of such combined activity.

**"Charitable Contribution Costs"** means Out-of-Pocket Expenses incurred by a Party in making any charitable contributions related to Commercialization of the Profit Share Product, including to support co-pay foundations and product donations.

"Collaboration Losses" means Losses (as defined in Section 14.1 of the Agreement) that arise out of the performance, in good faith, of the Commercialization of the Profit Share Product in the U.S. in accordance with the Agreement, excluding any such Losses that (a) are subject to indemnification by such Party pursuant to Section 14.1 or Section 14.2 of the Agreement or (b) are Product Liability Costs.

"**Data Costs**" means costs for product specific market research, market intelligence, in-market product usage and other data required to execute the U.S. Commercialization Plan.

"Distribution Costs" means the amount equal to [\*\*\*]% of Net Sales of the Profit Share Product in the U.S., which amount shall be deemed to have been incurred as Allowable Expenses by the Party that distributes the Profit Share Product in the U.S. It is understood that such amount is intended to cover all Commercial FTE Costs and Out-of-Pocket Expenses incurred by or on behalf of a Party that are attributable to the distribution to a Third Party of the Profit Share Product in the U.S., including: (i) handling and transportation to fulfill orders (excluding such costs, if any, treated as a deduction in the definition of Net Sales); (ii) customer services, including order entry, billing and adjustments, inquiry and credit and collection; and (iii) direct cost of storage and distribution of the Profit Share Product.

"Health Care Reform Fees" means Out-of-Pocket Expenses representing the annual fee paid to the U.S. government as defined in the PPACA and similar taxes and governmental fees in the United States, in each case to the extent directly attributable to the Profit Share Product and not included as a deduction in calculating Net Sales. If any similar governmental fee is legislated or rule created in any jurisdiction in the U.S., to the extent directly attributable to the Profit Share Product, this shall also be included as an Allowable Expense.

"Marketing Expenses" means Commercial FTE Costs and Out-of-Pocket Expenses identifiable to the advertising, promotion and marketing of the Profit Share Product in the U.S., and related professional education, in each case to the extent incurred specifically with respect to the Profit Share Product (and to the extent not performed by sales representatives), including:

- (a) **Advertising**, which includes Commercial FTE Costs and Out-of-Pocket Expenses associated with media costs, direct mails, production expenses, agency fees, and medical congresses and meetings;
- (b) **Promotion**, which includes Commercial FTE Costs and Out-of-Pocket Expenses associated with professional samples, public relations and communications expenses, development of information and data for national accounts, managed care organizations and group purchasing organizations;
- (c) **Market Research**, which includes Commercial FTE Costs and Out-of-Pocket Expenses associated with market information, focus groups, and market research professional staff and related Out-of-Pocket Expenses such as travel, business meals, and training;
- (d) **Marketing Management**, which includes the Commercial FTE Costs of the Profit Share Product management FTEs, to the extent directly performing activities with respect to the marketing of the Profit Share Product;

- (e) **Reimbursement/Access Services**, which includes Out-of-Pocket Expenses incurred to manage marketing programs and marketing costs (educational material) directly attributable to the Profit Share Product; *provided, however*, that, if employees of Fate or Janssen or any of their respective Affiliates provide this service, then the Commercial FTE Costs of such employees and the related Out-of-Pocket Expenses such as travel, business meals and entertainment will be included; and
- (f) **Health Policy/Advocacy**, which includes expenses reasonably necessary and identifiable to the Profit Share Product, such as advocacy sponsorships for the Profit Share Product's specific disease state and any specific policy lobbying and trade and government relations related expenses, in each case to the extent attributable to and specifically conducted with respect to the Profit Share Product.
- "Medical Affairs Expenses" means Commercial FTE Costs and Out-of-Pocket Expenses reasonably necessary and identifiable to the Profit Share Product incurred with respect to any Medical Affairs Activities in the U.S., excluding Commercial FTE Costs and Out-of-Pocket Expenses relating to Medical Affairs Studies.
- "Other Commercialization Costs" means any Commercial FTE Costs and Out-of-Pocket Expenses incurred with respect to the Profit Share Product that are approved by the USJCC or JSC and included in the U.S. Commercialization Plan and the U.S. Commercialization Budget, but that are not otherwise included in any other Allowable Expense category.
- "Other Income" means any payment or income (other than Net Sales) received by a Party or its Affiliate from a Third Party that is attributable to the Profit Share Product or is received in connection with the grant of a sublicense or other right or activity with respect to the Profit Share Product. For clarity, Other Income does not include payments by one Party or its Affiliate to the other Party or its Affiliate with respect to supply of the Profit Share Product.
- "Project Management, Alliance Management and Healthcare Compliance (HCC) Costs" means Commercial FTE Costs and Out-of-Pocket Expenses reasonably necessary and identifiable and attributable to the Profit Share Product incurred with respect to any Project Management, HCC and Alliance Management.
- "Recall Expenses" means Commercial FTE Costs and Out-of-Pocket Expenses directly associated with notification, retrieval and return of the Profit Share Product, destruction of such returned Profit Share Product, replacement Profit Share Product and distribution of the replacement Profit Share Product, in each case that are incurred with respect to a recall conducted in the U.S. in accordance with Section 5.1.7 of the Profit Share Product Exhibit. The Parties acknowledge that if the recall was not anticipated at the time the U.S. Commercialization Budget was established for a Calendar Year, then the Recall Expenses associated with such recall shall not be included for determining whether the Party conducting such recall has exceeded the amounts budgeted to be incurred by such Party in such Calendar Year for Allowable Expenses.

"Regulatory Maintenance Costs" means Commercial FTE Costs and Out-of-Pocket Expenses (including maintenance fees paid to a Regulatory Authority) relating to maintaining and enforcing Marketing Approval for the Profit Share Product in the U.S.

# "Selling Costs" means the following:

- (a) Total Commercial FTE Costs for sales representatives, which shall be the following percentages of Commercial FTE Costs of sales representatives Detailing the Profit Share Product in the U.S.: (i) [\*\*\*]% to the extent such sales representatives Detail only the Profit Share Product (and no other products); (ii) [\*\*\*]% to the extent such sales representatives Detail two products with the Profit Share Product as the First Position Detail; (iii) [\*\*\*]% to the extent such sales representatives Detail three or more products with the Profit Share Product as the First Position Detail; (iv) [\*\*\*]% to the extent such sales representatives Detail two products with the Profit Share Product as the Second Position Detail, (v) [\*\*\*]% to the extent such sales representatives Detail three or more products with the Profit Share Product as the Second Position Detail, and (vi) [\*\*\*]% to the extent such sales representatives Detail three or more products with the Profit Share Product as the Third Position Detail. For the avoidance of doubt, if a sales representative Details the Profit Share Product in different positions in different Details (e.g., First Position Detail in a portion of the Details and Second Position Details in other Details), then a pro rata share of the foregoing percentages, to be calculated based on the time spent by such sales representative on Detailing the Profit Share Product in each such position, will be included in Selling Costs. For periods in which U.S. sales representatives are performing activities in support of the Profit Share Product in the U.S., but are not Detailing the Profit Share Product in the U.S. (e.g., during launch preparation or training), the costs for such sales representatives will be allocated to Selling Costs based on the percentage of time such sales representatives are devoted to such activities in support of the Profit Share Product.
- (b) Commercial FTE Costs and Out-of-Pocket Expenses, other than Commercial FTE Costs for sales representatives included in (a) above, directly attributable to selling the Profit Share Product in the U.S., including first line sales managers, exhibits at shows or conventions including samples, charges for space, sales aids and brochures, sales meetings, specialty sales forces, consultants, call reporting and other Third Party monitoring/tracking services, and the like.

For purposes of the definition of Selling Costs, "**Detail**" means an interactive face-to-face visit by a sales representative with a medical professional having prescribing authority or who is able to influence prescribing decisions, within the target audience during which approved uses, safety, effectiveness, contraindications, side effects, warnings or other relevant characteristics of a pharmaceutical product are discussed in an effort to increase prescribing preferences of a pharmaceutical product for its approved uses. Detail includes First Position Details and Second Position Details. Activities conducted by medical support staff (such as medical science liaisons) will not constitute Details. E-details, activities conducted at conventions or similar gatherings and activities performed by market development specialists, managed care account directors and other personnel not performing face-to-face sales calls or not specifically trained with respect to a pharmaceutical product will not constitute Details. "Detailing" means the act of performing Details and to "Detail" mean to perform Details. For such purposes:

- (i) "**First Position Detail**" means a Detail in which the applicable pharmaceutical product is Detailed before any other product and the predominant portion of time is devoted to the Detailing of such pharmaceutical product.
- (ii) "Second Position Detail" means a Detail in which the applicable pharmaceutical product is Detailed in the second position (i.e., no more than one other product is presented to or discussed with the healthcare professional before the Profit Share Product) and the second most predominant portion of time is devoted to the Detailing of such pharmaceutical product.
- (iii) "**Third Position Detail**" means a Detail in which the applicable pharmaceutical product is Detailed in the third position (i.e., no more than two other products are presented to or discussed with the healthcare professional before the Profit Share Product) and the third most predominant portion of time is devoted to the Detailing of such pharmaceutical product.

"Supply Costs" means the sum of (a) Fate's Cost of Goods for Profit Share Product supplied by Fate to Janssen under any supply agreements for Commercialization in the U.S. and (b) Janssen's Cost of Goods for Profit Share Product manufactured by Janssen for Commercialization in the U.S.; *provided* that Supply Costs do not include [\*\*\*].

### (3) General Principles.

Each Party shall provide financial statements in such reporting format as the JFC may establish.

All calculations to be made pursuant to this Financial Exhibit shall be made in accordance with (i) the applicable definitions and terms set forth in this Financial Exhibit and in the Agreement in a manner consistent with the methodologies used for the U.S. Commercialization Budget as established by the JFC (first priority), (ii) the specific accounting policies as may be established by the JFC (second priority) and (iii) GAAP (third priority). All undefined terms shall be construed in accordance with GAAP, but only to the extent consistent with the other express terms and definitions in this Financial Exhibit, the Profit Share Product Exhibit and the Agreement and specific accounting policies established by the JFC.

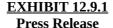
For the avoidance of doubt, income and withholding taxes imposed on either of the Parties or their Affiliates under the Agreement will not be included in the calculation of U.S. Pre-Tax Profits and Losses.

### (4) <u>Reconciliations</u>

The JFC will coordinate to resolve any differences in or disputes regarding the calculation of U.S. Pre-Tax Profits and Losses, or any component thereof. If the JFC is unable to resolve any such difference or dispute, the matter shall be subject to resolution pursuant to Section 2.6 of this Exhibit.

# EXHIBIT 11.8.1 Existing Agreements

[\*\*\*]
[\*\*\*]
[\*\*\*]
[\*\*\*]
[\*\*\*]
[\*\*\*]





# Fate Therapeutics Announces Worldwide Collaboration with Janssen for Novel iPSC-derived Cell-based Cancer Immunotherapies

□ Collaboration leverages Company's iPSC product platform and Janssen's proprietary tumor-targeting antigen binders to

create novel CAR NK and CAR T-Cell product candidates □
☐ Fate to receive \$50 million upfront payment and \$50 million equity investment, plus full funding for the research and development of collaboration candidates through IND filing ☐
□ Collaboration candidates to be developed against up to four tumor-associated antigens for hematologic malignancies and solid tumors □
☐ Fate eligible to receive payments of up to \$1.8 billion in development and regulatory milestones and up to \$1.2 billion in commercial milestone payments, plus double-digit royalties ☐

**San Diego, CA** – **April 2, 2020** – Fate Therapeutics, Inc. (NASDAQ: FATE), a clinical-stage biopharmaceutical company dedicated to the development of programmed cellular immunotherapies for cancer and immune disorders, announced today a global collaboration and option agreement with Janssen Biotech, Inc. (Janssen), one of the Janssen Pharmaceutical Companies of Johnson & Johnson.

Under the multi-year collaboration agreement, Janssen will contribute proprietary antigen binding domains for up to four tumor-associated antigen targets. The Company will apply its iPSC product platform to research and preclinically develop new iPSC-derived chimeric antigen receptor (CAR) NK and CAR T-cell product candidates. The Company will receive \$50 million in cash and \$50 million from the purchase by Johnson & Johnson Innovation – JJDC, Inc. of newly issued shares of the Company's common stock at a price per share of \$31.00. Janssen will also reimburse the Company for all activities conducted under the collaboration.

"We are delighted to enter this strategic collaboration, which brings together Janssen's scientific and global commercialization leadership, deep domain expertise in oncology and proprietary technologies for targeting and binding certain tumors and our industry-leading iPSC product platform to develop novel off-the-shelf CAR NK and T-cell cancer immunotherapies," said Scott Wolchko, President and Chief Executive Officer of Fate Therapeutics. "The collaboration strengthens our financial and operating position through a focused effort of developing cell-based cancer immunotherapies utilizing Janssen's proprietary antigen binding domains, while enabling us to continue to exploit our deep pipeline of wholly-owned product candidates and further develop our off-the-shelf, iPSC-derived cell-based immunotherapies."

The Company will advance candidates under the collaboration to the filing of an Investigational New Drug (IND) application, after which Janssen will have the right to exercise its option for an exclusive license for the development and commercialization of collaboration candidates targeting the tumor-associated antigens. The Company will be primarily responsible for the manufacture of collaboration candidates, the cost of which will be paid for by Janssen. The Company is eligible to receive payments of up to \$1.8 billion upon the achievement of development and regulatory milestones and up to \$1.2 billion upon the achievement of commercial milestones, plus double-digit royalties on worldwide commercial sales of products targeting the antigens. In addition, the Company has the right to elect to co-commercialize each collaboration candidate in the U.S. and share equally in profits and losses in the U.S., subject to its payment of certain clinical development costs and adjustments in milestone and royalty payments.

#### About Fate Therapeutics' iPSC Product Platform

The Company's proprietary induced pluripotent stem cell (iPSC) product platform enables mass production of off-the-shelf, engineered, homogeneous cell products that can be administered with multiple doses to deliver more effective pharmacologic activity, including in combination with cycles of other cancer treatments. Human iPSCs possess the unique dual properties of unlimited self-renewal and differentiation potential into all cell types of the body. The Company's first-of-kind approach involves engineering human iPSCs in a one-time genetic modification event and selecting a single engineered iPSC for maintenance as a clonal master iPSC line. Analogous to master cell lines used to manufacture biopharmaceutical drug products such as monoclonal antibodies, clonal master iPSC lines are a renewable source for manufacturing cell therapy products which are well-defined and uniform in composition, can be mass produced at significant scale in a cost-effective manner, and can be delivered off-the-shelf for patient treatment. As a result, the Company's platform is uniquely capable of overcoming numerous limitations associated with the production of cell therapies using patient- or donor-sourced cells, which is logistically complex and expensive and is subject to batch-to-batch and cell-to-cell variability that can affect clinical safety and efficacy. Fate Therapeutics' iPSC product platform is supported by an intellectual property portfolio of over 250 issued patents and 150 pending patent applications.

# **About Fate Therapeutics, Inc.**

Fate Therapeutics is a clinical-stage biopharmaceutical company dedicated to the development of first-in-class cellular immunotherapies for cancer and immune disorders. The Company has established a leadership position in the clinical development and manufacture of universal, off-the-shelf cell products using its proprietary induced pluripotent stem cell (iPSC) product platform. The Company's immuno-oncology product candidates include natural killer (NK) cell and T-cell cancer immunotherapies, which are designed to synergize with well-established cancer therapies, including immune checkpoint inhibitors and monoclonal antibodies, and to target tumor-associated antigens with chimeric antigen receptors (CARs). The Company's immuno-regulatory product candidates include ProTmune™, a pharmacologically modulated, donor cell graft that is currently being evaluated in a Phase 2 clinical trial for the prevention of graft-versus-host disease, and a myeloid-derived suppressor cell immunotherapy for promoting immune tolerance in patients with immune disorders. Fate Therapeutics is headquartered in San Diego, CA. For more information, please visit www.fatetherapeutics.com.

### **Forward-Looking Statements**

This release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 including statements relating to the expected benefits of the Company's collaboration with Janssen, the Company's expectations regarding future potential milestone and royalty payments under the collaboration, the objectives, plans and goals of the collaboration, the parties' rights and obligations under the collaboration, and the safety and therapeutic potential of the Company's iPSC product platform. These and any other forward-looking statements in this release 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, the risk that the Company may not comply with its obligations under and otherwise maintain its collaboration agreement with Janssen on the agreed upon terms, the risk that the Company may cease or delay planned development and clinical trials of any of its product candidates for a variety of reasons (including any delay in the Company's ability to conduct and complete preclinical studies and to enroll patients in current and planned clinical trials, requirements that may be imposed by regulatory authorities on the conduct of clinical trials or to support regulatory approval, difficulties in manufacturing or supplying the Company's product candidates for clinical testing, or the occurrence of any adverse events or other negative results that may be observed during development), the risk that Janssen or the Company may terminate the collaboration agreement for a variety of reasons, the risk that results observed in preclinical studies of its product candidates may not be replicated in ongoing or future clinical trials or studies, and the risk that its product candidates may not produce therapeutic benefits or may cause other unanticipated adverse effects. For a discussion of other risks and uncertainties, and other important factors, any of which could cause the Company's actual results to differ from those contained in the forward-looking statements, see the risks and uncertainties detailed in the Company's periodic filings with the Securities and Exchange Commission, including but not limited to the Company's most recently filed periodic report, and from time to time in the Company's press releases and other investor communications. Fate Therapeutics is providing the information in this release as of this date and does not undertake any obligation to update any forward-looking statements contained in this release as a result of new information, future events or otherwise.

#### **Contact:**

Christina Tartaglia Stern Investor Relations, Inc. 212.362.1200 christina@sternir.com

# **EXHIBIT 13.2.1** Fate Research Patents

[\*\*\*].

[***]	[***]	[***]
į j		
[***]		
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
5	51112	51117
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	
[*****]	[***]	
Edutotel	Fileday	
[***]	[***]	
	1	

[\*\*\*].

# SCHEDULE 5.3 Fate Confidential Methods

[***] [***]	[***] [***] [***] [***]
[***] [***]	[***] [***]
[***] [***] •	[***] [***] [***]
[***] [***] •	[***] [***] [***]
[***] [***] • •	[***] [***] [***]
[***] [***]	[***]
[***] [***] •	[***]

```
[***]
[***]
           [***]
           [***]
           [***]
[***]
[***]
[***]
           [***]
[***]
[***]
[***]
[***]
           [***]
                        [***]
[***]
                  0
                  0
                        [***]
                  0
                        [***]
                  0
                        [***]
[***]
                  0
                        [***]
                  0
                        [***]
                  0
            [***]
                        [***]
                  0
                        [***]
[***]
                  0
                  0
                        [***]
                  0
                        [***]
                  0
                        [***]
[***]
[***]
           [***]
            [***]
```

# SCHEDULE 5.3.7 **Janssen Confidential Methods**

[\*\*\*] [\*\*\*] [\*\*\*]

[\*\*\*] [\*\*\*]

[\*\*\*]

[\*\*\*]

[\*\*\*]

# SCHEDULE 10.6.2 Fate Licensor Patents

[

[***]	[***]	[***]
[***]		
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

[***]				
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]				
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]				
[***]	[***]	[***]		
[***]	[***]	[***]		
[***]	[***]			

[\*\*\*]

# SCHEDULE 13.2.11 Exclusions

- [\*\*\*]
- [\*\*\*]
- [\*\*\*]

#### STOCK PURCHASE AGREEMENT

This Stock Purchase Agreement (this "*Agreement*") is made as of April 2, 2020 (the "*Effective Date*"), by and between Fate Therapeutics, Inc., a Delaware corporation (the "*Company*"), having its principal place of business at 3535 General Atomics Court, Suite 200, San Diego, CA 92121, and Johnson & Johnson Innovation – JJDC, Inc., a New Jersey corporation (the "*Purchaser*"), having its principal place of business at 410 George Street, New Brunswick, New Jersey 08901.

**W**HEREAS, the Company and Janssen Biotech, Inc., an Affiliate of the Purchaser, have entered into that certain Collaboration and Option Agreement of even date herewith (the "*Collaboration Agreement*"); and

**Whereas,** the Company wishes to sell to the Purchaser, and the Purchaser wishes to purchase from the Company, shares of the Company's common stock, par value \$0.001 per share ("*Common Stock*"), on the terms and subject to the conditions set forth in this Agreement.

#### AGREEMENT

In consideration of the mutual covenants contained in this Agreement, and for other good and valuable consideration, the receipt of which is hereby acknowledged, the Company and the Purchaser hereby agree as follows:

### 1. **D**EFINITIONS

Capitalized terms used but not defined herein shall have the meanings provided in the Collaboration Agreement. In addition, the following terms shall have the respective meanings set forth below:

**1.1** "Affiliate" shall mean any Person that directly or indirectly is controlled by, controls or is under common control with either Company or Purchaser, as applicable, at the time the determination of affiliation is being made. For the purposes of this definition, the term "control" (including, with correlative meanings, the terms "controlled by" and "under common

1.

[\*\*\*] Certain information in this exhibit has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the registrant if publicly disclosed.

control with") as used with respect to a Person means (a) direct or indirect ownership of more than fifty percent (50%) of the voting securities, capital stock or equity interests of such Person or (b) possession, directly or indirectly, of the power to direct the management and policies of such Person, as applicable, whether through the ownership or control of voting securities, by contract or otherwise.

- **1.2** "*Aggregate Purchase Price*" shall mean the product of the Share Price multiplied by the number of Shares, rounded up to the nearest whole penny.
  - **"Closing"** shall have the meaning set forth in Section 2.3(a).
  - **"Closing Date"** shall have the meaning set forth in Section 2.3(a).
- **1.5** "*Exchange Act*" shall mean the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.
- **1.6** "Governmental Authority" shall mean any court, agency, authority, department, regulatory body or other instrumentality of any government or country or of any national, federal, state, provincial, regional, country, city or other political subdivision of any such government or country or any supranational organization of which any such country is a member.
- **1.7** "*Intellectual Property*" shall mean trademarks, trade names, trade dress, service marks, copyrights, and similar rights (including registrations and applications to register or renew the registration of any of the foregoing), patents and patent applications, trade secrets, and any other similar intellectual property rights.
- **1.8** "*Intellectual Property License*" shall mean any license, permit, authorization, approval, contract or consent granted, issued by or with any Person relating to the use of Intellectual Property.
- **1.9** "*Law*" or "*Laws*" shall mean all laws, statutes, rules, regulations, orders, judgments, injunctions and/or ordinances of any Governmental Authority.
  - **1.10** "*Nasdaq*" shall mean The Nasdaq Stock Market LLC.

- **1.11** "*Person*" shall mean any individual, corporation, limited liability company, partnership, association, trust, estate or other entity or organization.
  - **1.12** "*Rule 144*" shall have the meaning set forth in Section 4.8(a).
  - **1.13** "SEC" shall mean the U.S. Securities and Exchange Commission.
- **1.14** "SEC Filings" shall mean all reports, schedules, forms, statements and other documents filed or required to be filed by the Company with the SEC pursuant to the requirements of the Securities Act or the Exchange Act, including material filed pursuant to Section 13(a) or 15(c) of the Exchange Act, in each case, together with all exhibits, supplements, amendments and schedules thereto, and all documents incorporated by reference therein.
- **1.15** "Securities Act" shall mean the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.
  - **1.16** *"Shares"* shall have the meaning set forth in Section 2.3(a).
  - **1.17** "*Share Price*" shall mean \$31.00 per share of Common Stock.

#### 2. AGREEMENT TO SELL AND PURCHASE

- **2.1 Authorization of Shares.** The Company has authorized the sale and issuance to the Purchaser of the Shares under the terms and conditions of this Agreement.
- **2.2 Sale and Issuance of Shares.** On the basis of the representations and warranties herein, and upon the terms and subject to the conditions hereof, the Purchaser agrees to purchase from the Company, and the Company agrees to issue and sell to the Purchaser, the Shares at a price per share equal to the Share Price.

#### 2.3 Closing.

Closing. Subject to the satisfaction or waiver of the conditions set forth herein, the closing of the purchase and sale of the Shares (the "Closing") shall take place on the 5th calendar day following the Effective Date (or, if such 5th calendar day is not a business day, the next business day subsequent to such 5th calendar day) at the offices of the Company or at such earlier time and such other place as the Company and the Purchaser may agree in writing (the date of the Closing, the "Closing Date"). At the Closing, (i) the Company shall deposit 1,612,904 shares of Common Stock (or, in the event such number of shares would exceed 19.99% of the Company's total outstanding shares of Common Stock immediately prior to the Closing, such lesser whole number of shares as would be equal to the maximum number that could be issued without exceeding 19.99% of the Company's total outstanding shares of Common Stock immediately prior to the Closing) (the "Shares") with its transfer agent to be held in book entry form for the benefit of, and in the name of, the Purchaser and (ii) the Purchaser shall pay the Aggregate Purchase Price for the Shares in U.S. dollars by bank wire transfer in immediately available funds to a bank account designated by the Company. In the event of any stock dividend, stock split, combination of shares, recapitalization or other similar change in the capital structure of the Company after the date hereof and on or prior to the Closing Date that affects or relates to the Common Stock, the number of Shares and the Share Price shall be adjusted proportionately.

#### 3. Representations, Warranties and Covenants of the Company

The Company hereby represents and warrants to the Purchaser as follows:

**3.1 Organization, Good Standing and Qualification**. The Company is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware and has all requisite corporate power and authority to carry on its business. The Company is duly qualified to transact business as a corporation and is in good standing in each jurisdiction in which the failure so to qualify would have a material adverse effect upon the Company's ability to perform its obligations under this Agreement.

**3.2 Authorization; Due Execution.** The Company has the requisite corporate power and authority to enter into this Agreement and to perform its obligations under the terms of this Agreement. All corporate action on the part of the Company, its officers, directors and stockholders necessary for the authorization, execution and delivery of this Agreement has been taken. This Agreement has been duly authorized, executed and delivered by the Company and, upon due execution and delivery by the Purchaser, this Agreement will be a valid and binding obligation of the Company, enforceable in accordance with its terms, except as enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally or by equitable principles.

## 3.3 Capitalization and Voting Rights.

The capitalization of the Company is as set forth in the SEC Filings. The (a) authorized capital stock of the Company consists of 150,000,000 shares of Common Stock and 5,000,000 shares of preferred stock, par value \$0.001 per share, of the Company ("Preferred Stock"). As of the date hereof, 2,819,549 shares of Preferred Stock are designated as Class A Convertible Preferred Stock, of which 2,794,549 shares are issued and outstanding, and there are 75,967,614 shares of Common Stock issued and outstanding, of which no shares are owned by the Company. There are no other shares of any other class or series of capital stock of the Company issued and outstanding. All of the issued and outstanding shares of Common Stock have been duly authorized and validly issued and are fully paid and non-assessable. The Company has no capital stock reserved for issuance, except that, as of March 25, 2020, there are (i) 13,972,745 shares of Common Stock reserved for issuance upon the conversion of the Class A Convertible Preferred Stock, (ii) 11,920,860 shares of Common Stock reserved for issuance upon exercise of outstanding options and vesting of outstanding restricted stock units granted under the Company's 2007 Equity Incentive Plan, Amended and Restated 2013 Stock Option and Incentive Plan and Inducement Equity Plan (collectively, the "Equity Plans"), (iii) 4,348,973 shares of Common Stock available for future grant under the Equity Plans, (iv) 729,000 shares of Common Stock available for issuance under the Company's 2013 Employee Stock Purchase Plan and (v) zero shares of Common Stock reserved for issuance upon exercise of warrants outstanding. Except as stated above or in the SEC Filings, the Company is not obligated to (x) issue any additional options, warrants, calls, subscriptions or other rights to acquire shares of capital stock of, or other equity

interests in, the Company or (y) redeem, purchase, repurchase or otherwise acquire or cause to be acquired any capital stock of, or other equity interests in, the Company. The issuance of the Shares pursuant to this Agreement will not give rise to any preemptive rights or rights of first refusal on behalf of any third party. All of the authorized shares of Common Stock are entitled to one vote per share.

- (b) As of the date hereof, except as disclosed in the SEC Filings, there are not any restrictions on the transfer of capital stock of the Company other than pursuant to state and federal securities Laws.
- (c) The Company is not a party to or subject to any agreement or understanding relating to the voting of shares of capital stock of the Company or the giving of written consents by a stockholder or director of the Company.
- **3.4 Subsidiaries.** The Company has disclosed all of its subsidiaries required to be disclosed pursuant to Item 601(b)(21) of Regulation S-K in an exhibit to its Annual Report on Form 10-K (the "Subsidiaries" and each, a "Subsidiary"). Each Subsidiary (i) has been duly organized and is validly existing in good standing under the laws of the jurisdiction of its incorporation or organization, has corporate or similar power and authority to own, lease and operate its properties and to conduct its business as presently conducted, and (ii) is duly qualified to transact business and is in good standing in each jurisdiction in which such qualification is required, whether by reason of the ownership or leasing of property or the conduct of business, except where the failure to be so organized, existing or qualified would not, individually or in the aggregate, have a material adverse effect on the Company's ability to perform its obligations under this Agreement. All of the issued and outstanding capital stock of each Subsidiary has been duly authorized and validly issued, is fully paid and nonassessable and is owned by the Company, directly or through its Subsidiaries, and is free and clear of any security interest, mortgage, pledge, lien, encumbrance, claim or equity.

- **3.5 Valid Issuance of Stock.** The Shares, when issued, sold and delivered in accordance with the terms of Section 2 hereof for the consideration and on the terms and conditions set forth herein, will be duly and validly authorized and issued, fully paid and nonassessable and, based in part upon the representations of the Purchaser in this Agreement, will be issued in compliance with all applicable federal and state securities laws.
- **3.6 No Defaults**. There exists no default under the provisions of any instrument or agreement evidencing, governing or otherwise relating to any material indebtedness of the Company or any of its Subsidiaries. There exists no default under any other agreement to which the Company or any of its Subsidiaries is a party, which default would have a material adverse effect upon the Company's ability to perform its obligations under this Agreement.
- 3.7 **SEC Filings; Financial Statements.** Since January 1, 2017, the Company has timely filed with the SEC all SEC Filings. Such SEC Filings were prepared in accordance with and, as of the date on which each such SEC Filing was filed with the SEC, complied in all material respects with the applicable requirements of the Securities Act and Exchange Act. None of such SEC Filings, including, without limitation, any financial statements, exhibits and schedules included therein and documents incorporated therein by reference, at the time filed, declared effective or mailed, as the case may be, contained an untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading. The consolidated financial statements of the Company and its Subsidiaries included in its Annual Report on Form 10-K for the fiscal year ended December 31, 2019 comply as to form in all material respects with applicable accounting requirements and the published rules and regulations of the SEC with respect thereto, have been prepared in accordance with United States generally accepted accounting principles ("GAAP") applied on a consistent basis during the periods involved (except as may be indicated in the notes thereto) and fairly present in all material respects the financial position of the Company as of the dates thereof and the results of its operations and cash flows for the periods then ended. Except (i) as set forth in the SEC Filings or (ii) for liabilities incurred in the ordinary course of business subsequent to the date of the most recent balance sheet contained in the SEC Filings, the Company has no liabilities, whether absolute or accrued, contingent or otherwise, other than those that would not,

individually or in the aggregate, have a material adverse effect on the business, operations or financial condition of the Company and its Subsidiaries, taken as a whole. There are no material unconsolidated Subsidiaries of the Company or any material off-balance sheet arrangements of any type (including any off balance sheet arrangements required to be disclosed pursuant to Item 303(a)(4) of Regulation S-K promulgated under the Securities Act) that have not been so described in the SEC Filings filed prior to the date hereof nor any obligations to enter into any such arrangements.

- **3.8 Material Changes.** Since December 31, 2019, except as specifically disclosed in SEC Filings dated prior to the Effective Date and in Schedule 3.8 attached hereto: (i) there have been no events, occurrences or developments that have had or would reasonably be expected to have, either individually or in the aggregate, a material adverse effect on the business, operations or financial condition of the Company and its Subsidiaries, taken as a whole, (ii) the Company has not incurred any material liabilities (contingent or otherwise) other than (A) trade payables and accrued expenses incurred in the ordinary course of business consistent with past practice and (B) liabilities not required to be reflected in the Company's financial statements pursuant to GAAP or disclosed in filings made with the SEC, (iii) the Company has not altered materially its method of accounting or the manner in which it keeps its accounting books and records, (iv) the Company has not declared or made any dividend or distribution of cash, shares of capital stock or other property to its stockholders or purchased, redeemed or made any agreements to purchase or redeem any shares of its capital stock (other than in connection with repurchases of unvested stock issued to employees of the Company), and (v) the Company has not issued any equity securities, except Common Stock issued pursuant to existing Company equity incentive, stock option or stock purchase plans or agreements or executive and director compensation arrangements disclosed in the SEC Filings dated prior to the Effective Date.
- **3.9 Investment Company**. The Company is not, and immediately after receipt of payment for the Shares, will not be an "investment company" within the meaning of the Investment Company Act of 1940, as amended. The Company shall conduct its business in a manner so that it will not become subject to the Investment Company Act of 1940, as amended.

- **3.10 Registration Rights**. Other than as disclosed in the SEC Filings, no Person has any right to cause the Company to effect the registration under the Securities Act of the transfer of any securities of the Company.
- 12(b) of the Exchange Act, and the Company has taken no action designed to terminate the registration of the Common Stock under the Exchange Act nor has the Company received any notification that the SEC is contemplating terminating such registration. The Company has not, in the previous twelve (12) months, received (i) written notice from Nasdaq that the Company is not in compliance with the listing or maintenance requirements of Nasdaq that would result in immediate delisting or (ii) any notification, Staff Delisting Determination, or Public Reprimand Letter (as such terms are defined in applicable Nasdaq listing rules) that requires a public announcement by the Company of any noncompliance or deficiency with respect to such listing or maintenance requirements (other than any public announcement relating to noncompliance or deficiency under Rules 5605(b)(1), 5605(c)(2), 5450(a)(1), or 5250(c)(1) of the Nasdaq listing rules). The Company is in compliance with all listing and maintenance requirements of Nasdaq on the date hereof, except for any noncompliance or deficiency which may exist under Rules 5605(b)(1), 5605(c)(2), 5605(d)(2), 5450(a)(1), or 5250(c)(1) of the Nasdaq listing rules and in each such case where the Company fully expects to, and has a plan to, regain compliance in accordance with applicable Nasdaq procedures and cure periods such as to avoid any suspension of trading of the Company's Common Stock on Nasdaq or delisting actions by Nasdaq.
- **3.12 Private Placement**. Assuming the accuracy of Purchaser's representations and warranties set forth in Sections 4.4 4.7 hereof, the offer, sale and issuance of the Shares to be issued in conformity with the terms of this Agreement constitute transactions which are exempt from the registration requirements of the Securities Act and from all applicable state registration or qualification requirements. Neither the Company nor any Person acting on its behalf will take any action that would cause the loss of such exemption. The issuance and sale of the Shares hereunder does not contravene the rules and regulations of Nasdaq.

- **3.13 No Integrated Offering.** Assuming the accuracy of Purchaser's representations and warranties set forth in Sections 4.4 4.7 hereof, none of the Company nor, to the Company's knowledge, any of its Affiliates or any Person acting on its behalf has, directly or indirectly, at any time within the past six (6) months, made any offers or sales of any Company security or solicited any offers to buy any security under circumstances that would (i) eliminate the availability of the exemption from registration under Regulation D under the Securities Act in connection with the offer and sale by the Company of the Shares or (ii) cause the offering of the Shares to be integrated with prior offerings by the Company for purposes of any applicable law, regulation or stockholder approval provisions, including, without limitation, under the rules and regulations of Nasdaq.
- **3.14 OFAC**. Neither the Company nor, to the Company's knowledge, any director, officer, agent, employee, Affiliate or Person acting on behalf of the Company is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department ("**OFAC**"); and the Company will not directly or indirectly use the proceeds of the sale of the Shares, or lend, contribute or otherwise make available such proceeds to any Subsidiary, joint venture partner or other Person or entity, towards any sales or operations in Cuba, Iran, Syria, Sudan, Myanmar or any other country sanctioned by OFAC or for the purpose of unlawfully financing the activities of any Person that at the time of such financing is subject to any U.S. sanctions administered by OFAC.
- **3.15 FCPA.** Neither the Company nor, to the Company's knowledge, any agent or other Person acting on behalf of the Company, has: (i) directly or indirectly, used any funds for unlawful contributions, gifts, entertainment or other unlawful expenses related to foreign or domestic political activity, (ii) made any unlawful payment to foreign or domestic government officials or employees or to any foreign or domestic political parties or campaigns from corporate funds, (iii) failed to disclose fully any contribution made by the Company (or made by any Person acting on its behalf of which the Company is aware) which is in violation of law or (iv) violated in any material respect any provision of the Foreign Corrupt Practices Act of 1977, as amended.

- **3.16 Internal Accounting Controls.** The Company maintains a system of internal accounting controls sufficient to provide reasonable assurance that (i) transactions are executed in accordance with management's general or specific authorizations, (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain asset and liability accountability, (iii) access to assets or incurrence of liabilities is permitted only in accordance with management's general or specific authorization, and (iv) the recorded accountability for assets and liabilities is compared with the existing assets and liabilities at reasonable intervals and appropriate action is taken with respect to any differences.
- 3.17 Sarbanes-Oxley; Disclosure Controls. The Company is in compliance in all material respects with all of the provisions of the Sarbanes-Oxley Act of 2002, as amended, that are applicable to the Company. The Company has established disclosure controls and procedures (as such term is defined in Rule 13a-15(e) and 15d-15(e) under the Exchange Act) for the Company and designed such disclosure controls and procedures to ensure that information required to be disclosed by the Company in the reports 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. The Company's certifying officers have evaluated the effectiveness of the Company's disclosure controls and procedures as of the end of the period covered by the Company's most recently filed periodic report under the Exchange Act (such date, the "Evaluation Date"). The Company presented in its most recently filed periodic report under the Exchange Act the conclusions of the certifying officers about the effectiveness of the disclosure controls and procedures based on their evaluations as of the Evaluation Date. Since the Evaluation Date, there has been no change in the Company's internal control over financial reporting (as such term is defined in the Exchange Act) that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.
- **3.18 Litigation**. No action, suit, investigation or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any of its Subsidiaries or any of its or their property or any officer or director of the Company in their capacity as such (collectively, "*Actions*"), is pending or, to the knowledge of the Company, threatened, which if adversely determined would have a material adverse effect on the Company and its Subsidiaries, whether or not arising from transactions in the ordinary course of business.

There is no Action pending, or to the Company's best knowledge threatened, which if adversely determined could materially and adversely affect or challenge the legality, validity or enforceability of any of this Agreement or the Collaboration Agreement or the Company's ability to consummate the transactions contemplated by this Agreement or the Collaboration Agreement.

- 3.19 Licenses and Other Rights; Compliance with Laws. The Company and each Subsidiary has all franchises, permits, licenses and other rights and privileges ("*Permits*") necessary to permit it to own its properties and to conduct its business as presently conducted and is in compliance thereunder, except where the failure to be in compliance does not and would not have a material adverse effect on the Company. The Company and each Subsidiary has not taken any action that would interfere with the Company's ability to renew all such Permit(s), except where the failure to renew such Permit(s) would not have a material adverse effect on the Company. The Company and each Subsidiary is and has been in compliance with all Laws applicable to its business, properties and assets, except where the failure to be in compliance does not and would not have a material adverse effect on the Company.
- **3.20 No Governmental Authority or Third Party Consents.** No consent, approval, order or authorization of, or registration, qualification, designation, declaration or filing with, any federal, state, local or provincial Governmental Authority or other third party on the part of the Company or any of its Subsidiaries is required in connection with the authorization, execution and delivery by the Company of this Agreement and the Collaboration Agreement, or with the authorization, issue and sale by the Company of the Shares, except for such notices required or permitted to be filed with certain state and federal securities commissions after the Closing Date, which notices will be filed on a timely basis.

- **3.21 No Conflict.** The Company's execution, delivery and performance of this Agreement and the Collaboration Agreement, and compliance with the provisions hereof and thereof by the Company, do not and shall not: (a) violate any provision of applicable law or any ruling, writ, injunction, order, permit, judgment or decree applicable to the Company; (b) constitute a breach of, or default under (or an event which, with notice or lapse of time or both, would become a default under) or conflict with, or give rise to any right of termination, cancellation or acceleration of, any agreement, arrangement or instrument, whether written or oral, by which the Company or any of its assets are bound or (c) violate or conflict with any of the provisions of the Company's Amended and Restated Certificate of Incorporation or Amended and Restated Bylaws, each as amended to date, except, in the case of subsections (a) and (b), as would not have a material adverse effect on the Company.
- **3.22 Regulation M Compliance**. The Company has not, and to its knowledge no one acting on its behalf has, (i) taken, directly or indirectly, any action designed to cause or to result in the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of any of the Shares or (ii) sold, bid for, purchased, or paid any compensation for soliciting purchases of, any of the Shares.

## 3.23 Intellectual Property.

(a) The Intellectual Property that is owned by the Company or any Subsidiary is owned free from any liens or restrictions (other than any restrictions set forth in any Intellectual Property License relating to such Intellectual Property), and all of the Company's and its Subsidiaries material Intellectual Property Licenses are in full force and effect in accordance with their terms and are free of any liens or restrictions (other than any restrictions set forth in any such Intellectual Property Licenses), and neither the Company nor to the Company's knowledge any other party thereto, is in material breach of any such material Intellectual Property License, and no event has occurred that with notice or lapse of time or both would constitute such a breach or default thereunder or would result in the termination thereof or would cause or permit the acceleration or other change of any right or obligation of the loss of any benefit thereunder by the Company, except where any such failures to be in full force and effect, such liens or restrictions, such material breaches, and such events would not have a material

adverse effect on the Company. There is no material legal claim or demand of any Person pertaining to, or any proceeding which is pending (of which the Company has received notice or otherwise has knowledge) or, to the knowledge of the Company, threatened, (x) challenging the right of the Company in respect of any Company Intellectual Property, or (y) that claims that any default exists under any Intellectual Property License, except, in the case of (x) and (y) above, where any such claim, demand or proceeding would not have a material adverse effect on the Company.

- (b) (i) The Company or one of its Subsidiaries (x) owns, free and clear of any lien or encumbrance, (y) has a valid license to, or has an enforceable right, to use, as it is used or held for use, or (z) can acquire on commercially reasonable terms sufficient rights to, all valid U.S. and non-U.S. patents, trade secrets, know-how, trademarks, service marks, copyrights, and other proprietary and intellectual property rights, and all grants with respect to the foregoing (collectively, the "*Proprietary Rights*") known by the Company to be necessary for the conduct of the Company's business, the absence of which would not have or reasonably be expected to have a material adverse effect on the Company (such Proprietary Rights owned by or licensed to the Company collectively, the "*Company Rights*"); and (ii) the Company and its Subsidiaries has taken reasonable measures to protect the Company Rights, consistent with prudent commercial practices in the biotechnology industry, except where failure to take such measures would not have or reasonably be expected to have a material adverse effect on the Company.
- **3.24 Material Contracts**. Each franchise, contract or other document of a character required to be described in the SEC Filings or to be filed as an exhibit to the SEC Filings under the Securities Act and the rules and regulations promulgated thereunder (collectively, the "*Material Contracts*") is so described in all material respects or filed. The Company is in compliance with and not in default of its obligations under the Material Contracts, except where any such non-compliance or default would not have a material adverse effect on the Company.

**Health Laws and FDA Compliance**. Except as would not, individually or in the aggregate, result 3.25 in a material adverse effect on the Company: (i) each of the Company and each of its Subsidiaries is and has been in compliance with statutes, laws, ordinances, rules and regulations applicable to the Company or its Subsidiaries for the ownership, testing, development, manufacture, packaging, processing, use, labeling, storage, or disposal of any product manufactured by or on behalf of the Company and its Subsidiaries or out-licensed by the Company and its Subsidiaries (each a "Company Product"), including without limitation, the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, et seq., and the Public Health Service Act, 42 U.S.C. § 262 (collectively, "Applicable Health Laws"); (ii) the Company and its Subsidiaries possess all licenses, certificates, approvals, authorizations, permits and supplements or amendments thereto required by any such Applicable Health Laws and/or for the ownership of their properties or the conduct of their business as it relates to a Company Product and as described in the SEC Filings (collectively, "Authorizations") and such Authorizations are valid and in full force and effect and neither the Company nor any of its Subsidiaries is in violation of any term of any such Authorizations; (iii) neither the Company nor any of its Subsidiaries has received any written notice of adverse finding, warning letter or other written correspondence or notice from the U.S. Food and Drug Administration (the "FDA") or any other Governmental Authority alleging or asserting noncompliance with any Applicable Health Laws or Authorizations relating to a Company Product; (iv) neither the Company nor any of its Subsidiaries has received written notice of any ongoing claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any Governmental Authority or third party alleging that any Company Product, operation or activity related to a Company Product is in violation of any Applicable Health Laws or Authorizations; and (v) neither the Company nor any of its Subsidiaries has received written notice that any Governmental Authority has taken, is taking or intends to take action to limit, suspend, modify or revoke any Authorizations.

- 3.26 Tests and Preclinical and Clinical Trials. The studies, tests and preclinical and clinical trials conducted by or, to the Company's knowledge, on behalf of the Company that are described in the SEC Filings were and, if still pending, are being, conducted in all material respects in accordance with any applicable protocols submitted to the FDA or any Governmental Authority exercising comparable authority, procedures and controls pursuant to, where applicable, accepted professional and scientific standards, and all applicable Laws and regulations; the descriptions of the studies, tests and preclinical and clinical trials conducted by or, to the Company's knowledge, on behalf of the Company, and the results thereof, contained in the SEC Filings are accurate and complete in all material respects; to the Company's knowledge, there are no subsequent studies, tests or preclinical and clinical trials, the results of which call into question in any material respect the results described in the SEC Filings; and the Company has not received any notices or correspondence from the FDA, any Governmental Authority exercising comparable authority or any Institutional Review Board requiring the termination, suspension, material modification or clinical hold of any studies, tests or preclinical or clinical trials currently being conducted by or on behalf of the Company.
- **3.27 Taxes.** (i) the Company and its Subsidiaries have filed all tax returns that are required to have been filed by each of them or has requested extensions of the filing date thereof and (ii) the Company and its Subsidiaries have paid all taxes required to be paid by any of them and any other assessment, fine or penalty levied against any of them, to the extent that any of the foregoing is due and payable, except in the case of clause (i) and (ii), for any such assessment, fine or penalty that is currently being contested in good faith or as would not have a material adverse effect on the Company, whether or not arising from transactions in the ordinary course of business and (iii) there are no tax audits ongoing of which the Company has received written notice.
- **3.28 Transfer Taxes.** There are no transfer taxes or other similar fees or charges under federal law or the laws of any state, or any political subdivision thereof, required to be paid in connection with the execution and delivery of this Agreement or the issuance or sale by the Company of the Shares.

- **3.29 Insurance.** The Company and its Subsidiaries are insured by insurers of recognized financial responsibility against such losses and risks and in such amounts as are reasonable and customary in the business in which it is engaged; all policies of insurance and fidelity or surety bonds insuring the Company and its Subsidiaries or their businesses, assets, employees, officers and directors are in full force and effect; the Company and its Subsidiaries are in compliance with the terms of such policies and instruments in all material respects; and there are no claims by the Company or any of its Subsidiaries under any such policy or instrument as to which any insurance company is denying liability or defending under a reservation of rights clause; neither the Company nor any of its Subsidiaries has been refused any insurance coverage sought or applied for; and the Company has no reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business at a cost that would not have a material adverse effect on the Company, whether or not arising from transactions in the ordinary course of business.
- **3.30 Related Party Transactions**. No director or Affiliate of the Company, nor any family member of any officer, director or Affiliate of the Company has entered into any transaction with the Company or any of its Subsidiaries that would be required to be disclosed under Item 404 of Regulation S-K that has not been disclosed in the SEC Filings as required by the rules and regulations of the SEC.
- **3.31 Labor**. Neither the Company nor any of its Subsidiaries is bound by or subject to any collective bargaining agreement or any similar agreement with any organization representing its employees. No labor problem or dispute with the employees of the Company and its Subsidiaries exists or, to the knowledge of the Company, is threatened, and the Company is not aware of any existing or imminent labor disturbance by the employees of any of its principal suppliers or contractors, that would have a material adverse effect on the Company, whether or not arising from transactions in the ordinary course of business, except as contemplated in the SEC Filings.

- **3.32 Environmental Laws**. The Company and each of its Subsidiaries (i) is in compliance with any and all applicable foreign, federal, state and local laws and regulations relating to the protection of human health and safety, the environment or hazardous or toxic substances or wastes, pollutants or contaminants ("*Environmental Laws*"), (ii) has received and is in compliance with all permits, licenses or other approvals required of them under applicable Environmental Laws to conduct its business and (iii) has not received notice of any actual or potential liability under any environmental law, except where such non-compliance with Environmental Laws, failure to receive required permits, licenses or other approvals, or liability would not, individually or in the aggregate, have a material adverse effect on the Company, whether or not arising from transactions in the ordinary course of business. The Company has not been named as a "potentially responsible party" under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended.
- **3.33 No Disqualification Events.** With respect to the Shares to be offered and sold hereunder in reliance on Rule 506 under the Securities Act, none of the Company or any of its predecessors, and to the knowledge of the Company, any affiliated issuer, director, executive officer, other officer of the Company participating in the offering hereunder, beneficial owner of 20% or more of the Company's outstanding voting equity securities, calculated on the basis of voting power, nor any promoter (as that term is defined in Rule 405 under the Securities Act) connected with the Company in any capacity at the time of sale (each, an "*Issuer Covered Person*" and, together, "*Issuer Covered Persons*") is subject to any of the "Bad Actor" disqualifications described in Rule 506(d)(1)(i) to (viii) under the Securities Act (a "*Disqualification Event*"), except for a Disqualification Event covered by Rule 506(d)(2) or (d)(3). The Company has exercised reasonable care to determine whether any Issuer Covered Person is subject to a Disqualification Event. The Company has complied, to the extent applicable, with its disclosure obligations under Rule 506(e), and has furnished to the Purchaser a copy of any disclosures provided thereunder.
- **3.34 Other Covered Persons**. Except to attorneys for legal services, the Company is not aware of any person that has been or will be paid (directly or indirectly) remuneration in connection with the sale of any Regulation D Shares pursuant to this Agreement.

- **3.35 Shell Company**. As of the date hereof and the Closing Date, the Company is not a "shell company" nor a former "shell company" (as defined in Rule 405 of the Securities Act) and has never been a "shell company."
- **3.36 Application of Takeover Provisions.** The Company and the Company's Board of Directors have taken all necessary action in order to render inapplicable any control share acquisition, business combination, poison pill (including any distribution under a rights agreement) or other similar anti-takeover provision under the Company's Amended and Restated Certificate of Incorporation or the Laws of its state of incorporation that is or could become applicable to the Purchaser as a result of the Purchaser and the Company fulfilling their obligations or exercising their rights under this Agreement, including without limitation as a result of the Company's issuance of the Shares and the Purchaser's ownership of the Shares.
- **3.37 Passive Foreign Investment Company; Controlled Foreign Company**. Neither the Company nor its Subsidiaries will be deemed to constitute a "passive foreign investment company" within the meaning of 26 USC §1297(a) or a "controlled foreign company" within the meaning of 26 USC §957.
- **3.38 Full Disclosure**. The Company understands that the Purchaser will rely on the foregoing representations in effecting the purchase of the Shares. Except to the extent specifically disclosed in Schedule 3.8 hereto, no representation or warranty of the Company in this Agreement and the Collaboration Agreement, when taken together with the SEC Filings, contains any untrue statement of a material fact or omits to state any material fact necessary in order to make the statements contained herein or therein, in light of the circumstances under which they were made, not misleading.

#### 4. Representations, Warranties and Covenants of the Purchaser

The Purchaser hereby represents and warrants to the Company as of the Closing Date as follows:

**4.1 Organization and Good Standing**. The Purchaser is a corporation duly organized, validly existing and in good standing under the laws of its jurisdiction of incorporation and has all requisite corporate power and authority to carry on its business.

- **4.2 Authorization; Due Execution.** The Purchaser has the requisite corporate power and authority to enter into this Agreement and to perform its obligations under the terms of this Agreement. All corporate action on the part of the Purchaser, its officers, directors and stockholders necessary for the authorization, execution and delivery of this Agreement have been taken. This Agreement has been duly authorized, executed and delivered by the Purchaser, and, upon due execution and delivery by the Company, this Agreement will be a valid and binding obligation of the Purchaser, enforceable in accordance with its terms, except as enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally or by equitable principles.
- **4.3 No Current Ownership in the Company.** Other than the Shares acquired under this Agreement, neither the Purchaser, nor to the Purchaser's knowledge, any of its Affiliates own any shares of Common Stock or any rights to acquire Common Stock. To the Purchaser's knowledge, the purchase of the Shares will not result in the Purchaser (individually or together with any other Person with whom the Purchaser has identified, or will have identified, itself as part of a "group" in a public filing made with the SEC involving the Company's securities) acquiring, or obtaining the right to acquire, in excess of 19.999% of the outstanding shares of Common Stock or the voting power of the Company on a post transaction basis that assumes that the Closing shall have occurred. Such Purchaser does not presently intend to, alone or together with others, make a public filing with the SEC to disclose that it has (or that it together with such other Persons have) acquired, or obtained the right to acquire, as a result of such Closing (when added to any other securities of the Company that it or they then own or have the right to acquire), in excess of 19.999% of the outstanding shares of Common Stock or the voting power of the Company on a post transaction basis that assumes that the Closing shall have occurred.

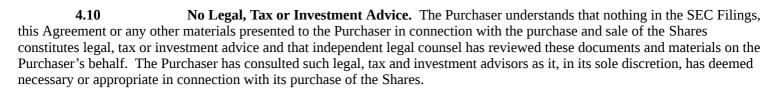
- **4.4 Purchase Entirely for Own Account.** This Agreement is made with the Purchaser in reliance upon the Purchaser's representation to the Company, which the Purchaser hereby confirms by executing this Agreement, that the Shares purchased by the Purchaser will be acquired for investment for the Purchaser's own account, not as a nominee or agent, and not with a view to the resale or distribution of any part thereof, and that the Purchaser has no present intention of selling, granting any participation in, or otherwise distributing the same. Purchaser does not have any contract, undertaking, agreement or arrangement with any Person to sell, transfer or grant participation to such Person or to any third party, with respect to the Shares, if issued.
- 4.5 **Disclosure of Information.** The Purchaser has received all the information that it has requested and that it considers necessary or appropriate for deciding whether to enter into this Agreement and to acquire the Shares. The Purchaser further represents that it has had an opportunity to ask questions and receive answers from the Company regarding the terms and conditions of the offering of the Shares; provided, however, that neither such inquiries nor any other investigation conducted by or on behalf of the Purchaser or its representatives or counsel shall modify, amend or affect Purchaser's right to rely on the truth, accuracy and completeness of the Company's representations and warranties contained in this Agreement or the Collaboration Agreement.
- **4.6 Investment Experience.** The Purchaser acknowledges that it is able to fend for itself, can bear the economic risk of its investment and has such knowledge and experience in financial or business matters that it is capable of evaluating the merits and risks of the investment in the Shares. The Purchaser has not been organized solely for the purpose of acquiring the Shares.
- **4.7 Accredited Investor.** The Purchaser is an "accredited investor" as such term is defined in Rule 501 of the General Rules and Regulations promulgated by the SEC pursuant to the Securities Act.

#### **4.8 Restricted Securities.** The Purchaser understands that:

- (a) the Shares will not be registered under the Securities Act by reason of a specific exemption therefrom, and that the Purchaser must, therefore, bear the economic risk of such investment, unless and until a subsequent disposition thereof is registered under the Securities Act or is exempt from such registration, such as under Rule 144 of the Securities Act ("Rule 144");
- **(b)** each book entry entitlement representing the Shares will be noted with the following legends:
- (i) THE SECURITIES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933 (THE "ACT") AND MAY NOT BE OFFERED, SOLD OR OTHERWISE TRANSFERRED, ASSIGNED, PLEDGED OR HYPOTHECATED UNLESS AND UNTIL REGISTERED UNDER THE ACT OR UNLESS THE COMPANY HAS RECEIVED AN OPINION OF COUNSEL SATISFACTORY TO THE COMPANY AND ITS COUNSEL THAT SUCH REGISTRATION IS NOT REQUIRED; and
- (ii) Any legend required to be placed thereon under applicable state securities laws.

(c) The Company will instruct its transfer agent not to register the transfer of the Shares (or any portion thereof) unless the conditions specified in the foregoing legends are satisfied, until such time as a transfer is made, pursuant to the terms of this Agreement, and in compliance with Rule 144 or pursuant to a registration statement or, if the opinion of counsel referred to above is to the further effect that such legend is not required in order to establish compliance with any provisions of the Securities Act or this Agreement.

**4.9 No Short Sales.** The Purchaser has not engaged, and will not engage, in any short sales of the Company's Common Stock within the three-month period prior to the Closing Date.

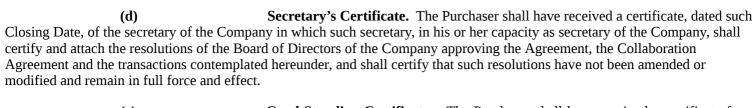


#### 5. CONDITIONS TO THE COMPANY'S OBLIGATIONS AT CLOSING

- **5.1 Closing**. The Company's obligation to sell, issue and deliver the Shares to the Purchaser at the Closing shall be subject to the following conditions to the extent not waived by the Company:
- **Receipt of Payment**. The Company shall have received payment in full, by wire transfer of immediately available funds, for the Shares at the Share Price.
- **(b) Collaboration Agreement.** The Collaboration Agreement shall have been executed and delivered by the Company and the Purchaser and shall remain in full force and effect.
- **Representations and Warranties; Obligations.** The representations and warranties made by the Purchaser in Section 4 hereof shall be true and correct on the Closing Date. The Purchaser shall have performed and complied with all obligations and conditions required to be performed and complied with by the Purchaser under this Agreement on, as of or prior to the Closing Date.

## 6. Conditions to the Purchaser's Obligations At Closing

- **6.1 Closing.** The Purchaser's obligation to accept delivery of and pay for the Shares at the Closing shall be subject to the following conditions to the extent not waived by the Purchaser:
- **(a) Collaboration Agreement.** The Collaboration Agreement shall have been executed and delivered by the Company and the Purchaser and shall remain in full force and effect.
- **Representations and Warranties; Obligations.** The representations and warranties made by the Company in Section 3 hereof shall be true and correct on the Closing Date. The Company shall have performed and complied with all obligations and conditions to be performed and complied with by the Company under this Agreement on, as of or prior to the Closing Date.
- **(c) Compliance Certificate.** The Purchaser shall have received a certificate, dated such Closing Date, of an executive officer of the Company in which such officer, in his or her capacity as an officer of the Company, shall state that: (i) the representations and warranties of the Company in this Agreement are true and correct; and (ii) the Company has complied with all agreements and satisfied all conditions on its part to be performed or satisfied hereunder on, as of or prior to such Closing Date in all material respects.



- **(e) Good Standing Certificate.** The Purchaser shall have received a certificate from the Secretary of State of the State of Delaware dated within three (3) business days of such Closing Date evidencing the good standing and legal corporate existence of the Company.
- **Opinion of Counsel to the Company.** The Purchaser shall have received an opinion, dated such Closing Date, of Goodwin Procter LLP, counsel for the Company, in the form attached hereto as Exhibit A.
- (g) Listing. The Company's Common Stock shall be listed and trade on the Nasdaq

Global Market.

#### 7. Additional Covenants.

### 7.1 Participation Right.

**Company Participation Right**. In the event that the Company intends to consummate, on or before the date twelve (12) months after the Closing Date, an underwritten public offering of shares of its Common Stock pursuant to an effective registration statement under the Securities Act that would result in aggregate gross proceeds (together with the proceeds from any shares of Common Stock sold pursuant to this Section 7.1) to the Company of at least \$150,000,000 (a "Follow-On Offering"), the Company shall have the right (the "Company Participation Right"), but not the obligation, to require that the Purchaser purchase, in a concurrent private placement exempt from the registration requirements of the Securities Act, an aggregate of \$50,000,000 of the Company's Common Stock (the "Participation Right **Shares**") on the same terms and at a price per share equal to the price at which the Common Stock is issued and sold to the public in the Follow-On Offering at a closing to be held concurrently with the closing of the Follow-On Offering (the "Participation **Right Closing**"). Notwithstanding the foregoing, to the extent that the number of shares of Common Stock that the Purchaser shall be obligated to purchase under this Section 7.1 would result in the Purchaser, together with its Affiliates, beneficially owning in excess of 14.999% of the outstanding shares of Common Stock or of the voting power of the Company (the "Maximum Ownership"), then, unless the Purchaser otherwise agrees, the actual number of Participation Right Shares to be purchased by the Purchaser under this Section 7.1 shall be reduced to the extent necessary to result in such beneficial ownership not exceeding the Maximum Ownership. The Company shall provide the Purchaser with written notice of the Company's decision as to whether it will exercise the Company Participation Right at least fifteen (15) days prior to the date of the Follow-On Offering closing, as such Participation Right Closing date may be delayed pursuant to Section 7.1(b)(ii).

## (b) Undertakings in Connection with Participation Right.

(i) In the event that the Company exercises its right under Section 7.1(a), the Company and the Purchaser shall, on or before the date of the final prospectus relating to such Follow-On Offering, execute and deliver a stock purchase agreement containing representations, warranties and conditions to closing, that are substantially similar to the representations, warranties and conditions in this Agreement and are reasonably satisfactory to the Company and the Purchaser.

Affiliates) shall use its reasonable best efforts to file, within ten (10) business days after any written request from the Company to Purchaser specifying that the Company reasonably anticipates exercising the Company Participation Right within three (3) months from the date of such request, any premerger notification and report forms required under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, including the rules and regulations thereunder, and any similar filings required under foreign antitrust or competition laws and regulations in connection with such exercise of the Company Participation Right (together, the "Antitrust Filings"). The parties shall cooperate in the timely preparation and submission of any necessary Antitrust Filings, and each shall request early termination of any applicable waiting period(s) relating to the Antitrust Filings. The obligation of each of the Company and the Purchaser to consummate the private placement pursuant to the Company Participation Right is subject to, and the Participation Right Closing shall occur on the later of the closing of the Follow-On Offering or the first business day after the expiration or early termination of any applicable waiting period(s) relating to the Antitrust Filings.

(iii) Each of the Company and the Purchaser shall promptly supply the other with any information that may be required in order to effectuate or obtain any applicable consents in connection with all required Antitrust Filings. Except where prohibited by applicable laws, and subject to the confidentiality obligations in the Collaboration Agreement and any joint defense agreement entered into between the parties, each of the Company and the Purchaser (and their respective Affiliates), in order to comply with any applicable antitrust or competition laws and regulations or obtain any applicable consents in connection with all required Antitrust

Filings, shall (A) consult with the other prior to taking a position with respect to any Antitrust Filings or applicable antitrust or competition laws and regulations, (B) to the extent reasonably required to permit appropriate coordination of efforts, permit the other to review and discuss in advance, and consider in good faith the views of the other in connection with, any analyses, appearances, presentations, memoranda, briefs, white papers, arguments, opinions, and proposals before making or submitting any of the foregoing to any Governmental Authority, (C) coordinate with the other in preparing and exchanging such information, (D) promptly provide the other (and their counsel) with copies of presentations or other advocacy submissions (and a summary of any oral presentations) made by such party to any Governmental Authority, and (E) promptly provide the other (and their counsel) with advance notice of, and an opportunity to attend as an observer (to the extent permitted by the applicable Governmental Authority), any meeting with any Governmental Authority in connection with the consummation of the private placement pursuant to the Company Participation Right. Each of the Company and the Purchaser (and their respective Affiliates) will notify the other promptly upon the receipt of (x) any comments from any Governmental Authority in connection with any Antitrust Filings made pursuant to this Agreement, and (y) any request by any Governmental Authority for amendments or supplements to any Antitrust Filings made pursuant to, or for information provided to comply in all material respects with, any applicable antitrust or competition laws and regulations.

Each of the Company and the Purchaser shall use all reasonable best efforts to take, or cause to be taken, all actions, and to do, or cause to be done, and to assist and cooperate with the other party in doing, all things necessary, proper, or advisable to consummate and make effective, in the most expeditious manner practicable, the private placement pursuant to the Company Participation Right, including using all reasonable best efforts to (A) obtain all consents, approvals, or waivers from third parties, including any applicable consents in connection with all required Antitrust Filings, (B) defend any actions challenging this Agreement or the consummation of the private placement pursuant to the Company Participation Right, and (C) execute or deliver any additional instruments necessary to consummate the private placement pursuant to the Company Participation Right, and to fully carry out the purposes of, this Agreement. The Purchaser shall treat all notices delivered under this Section 7.1, including the fact that the Company intends to or anticipates conducting a Follow-On Offering as set forth therein, as Confidential Information of the Company, as defined in, and in accordance with the terms of, the Collaboration Agreement.

**Restricted Transactions**. From and after the Closing Date and through the earlier of (i) six (6) months after the effective date of the Collaboration Agreement or (ii) the expiration or termination of the Collaboration Agreement, , the Purchaser shall not, and shall not authorize, instruct, facilitate or permit any of its Affiliates or any other person or entity to, engage in any of the following: (a) offer, pledge, sell or contract to sell the Shares or any other securities of the Company or any of its Affiliates or successors or any instruments convertible into or exchangeable or exercisable for securities of the Company or any of its Affiliates or successors (the "*Company Securities*"); (b) sell any option or contract to purchase, purchase any option or contract to sell, or grant any option, right or warrant for the sale of, or otherwise dispose of or transfer any of the Company Securities; or (c) enter into any swap or any other agreement or any transaction that transfers, in whole or in part, directly or indirectly, the economic consequence of ownership of the Company Securities, whether any such swap or transaction is to be settled by delivery of Common Stock or other securities, in cash or otherwise; provided, however, that the foregoing shall not prohibit the Purchaser or its Affiliates from transferring the Company Securities to an Affiliate of the Purchaser if such transferee Affiliate executes an agreement with the Company to be bound by the restrictions set forth in this Section 7.2. In the event that the Purchaser acquires Participation Right Shares, from and after the date

of the Participation Right Closing and through the earlier of (i) six (6) months after the date of the Participation Right Closing or (ii) the expiration or termination of the Collaboration Agreement, the Purchaser shall not, and shall not authorize, instruct, facilitate or permit any of its Affiliates or any other person or entity to, engage in the offer, pledge, sell or contract to sell the Participation Right Shares; provided, however, that the foregoing shall not prohibit the Purchaser or its Affiliates from transferring the Participation Right Shares to an Affiliate of the Purchaser if such transferee Affiliate executes an agreement with the Company to be bound by the restrictions set forth in this Section 7.2.

- **7.3 Market Stand-Off.** If requested by the representative of the underwriters of Common Stock (or other securities) of the Company in a registered offering of the Company's securities, provided that Purchaser is then a beneficial owner of 5% or greater of the Company's outstanding Common Stock, the Purchaser shall not sell or otherwise transfer or dispose of any Common Stock (or other securities) of the Company held by the Purchaser for a period specified by the representative of the underwriters, in any case not to exceed ninety (90) days following any registered offering of the Common Stock of the Company, provided that all executive officers, directors and all stockholders which then beneficially own 5% or greater of the Company's outstanding Common Stock (excluding investment companies or institutional investors that are not venture capital firms) are bound by substantially the same lock-up agreement. The Company may impose stop-transfer instructions with respect to the shares of Common Stock (or other securities) subject to the foregoing restriction until the end of said periods.
- **7.4 Shareholder Rights Plan.** No claim will be made or enforced by the Company or, with the consent of the Company, any other Person, that the Purchaser is an "Acquiring Person" under any control share acquisition, business combination, poison pill (including any distribution under a rights agreement) or similar anti-takeover plan or arrangement in effect or hereafter adopted by the Company, or that the Purchaser could be deemed to trigger the provisions of any such plan or arrangement, in either case solely by virtue of Purchaser purchasing the Shares under this Agreement.

- **7.5 Nasdaq Listing.** In the time and manner required by Nasdaq, the Company shall prepare and file with Nasdaq an additional shares listing application covering all of the Shares and shall use its reasonable best efforts to take all steps necessary to cause all of the Shares to be approved for listing on Nasdaq. The Company shall maintain compliance with all listing and maintenance requirements of Nasdaq on the date hereof, except for any noncompliance or deficiencies that may occur under Rules 5605(b)(1), 5605(c)(2), 5605(d)(2), 5450(a)(1), or 5250(c)(1) of the Nasdaq listing rules and in the event of any noncompliance or deficiency pursuant to such rules the Company shall use its reasonable best efforts to regain compliance in accordance with applicable Nasdaq procedures and cure periods such as to avoid any suspension of trading of the Company's Common Stock on Nasdaq or delisting actions by Nasdaq.
- **Legend Removal.** The legends set forth in Section 4.8(b) above shall be removed and the Company shall instruct its transfer agent for the Common Stock (the "Transfer Agent") to register the Shares in book-entry form free and clear of such legends or any other legends by electronic delivery at the applicable balance account at the Depository Trust Company, if (i) such Shares have been resold under an effective registration statement under the Securities Act, (ii) such Shares are sold or transferred in connection with a resale transaction in compliance with Rule 144 (if the transferor is not an Affiliate of the Company), (iii) such Shares are eligible for resale under Rule 144, without the requirement for the Company to be in compliance with the current public information required under Rule 144 as to such Shares and without volume or manner-of-sale restrictions or (iv) if such legend is not required under applicable requirements of the Securities Act (including judicial interpretations and pronouncements issued by the staff of the SEC). The Company further agrees that it shall cause its counsel (i) after the effective date of a registration statement registering the resale of the Shares, to issue to the Transfer Agent, if required by the Transfer Agent, a "blanket" legal opinion or other letter to allow sales without restriction pursuant to the effective registration statement and (ii) provide all other opinions of counsel as may reasonably be required by the Transfer Agent in connection with the removal of legends pursuant to this Section 7.6. Following Rule 144 becoming available for the resale of the Shares without the requirement for the Company to be in compliance with the current public information required under Rule 144 as to the Shares and without volume or manner-of-sale restrictions, the Company, upon the request of the Purchaser, shall issue, or shall cause Company counsel or other counsel satisfactory to the

Transfer Agent to issue to the Transfer Agent a letter of instruction stating that any and all restrictive legends under the Securities Act may be removed. Any fees (with respect to the Transfer Agent, Company counsel or otherwise) associated with the issuance of such opinion or the removal of such legends shall be borne by the Company. The Company may not make any notation on its records or give instructions to the Transfer Agent that enlarge the restrictions on transfer set forth in Section 4.8(b).

# 7.7 Registration Rights.

- **(a) Registration Statement**. So long as the Collaboration Agreement remains in effect, the Company shall:
- (i) file, and use its reasonable best efforts to cause to be declared effective, a registration statement with the SEC (the "*Registration Statement*") on or before the date that is eighteen (18) months following the Effective Date to register the Shares and the Participation Right Shares, if any, then owned by the Purchaser (collectively, the "*Registrable Shares*") on Form S-3 under the Securities Act, or on such other form which is appropriate to register such Registrable Shares for resale from time to time by the Purchaser;
- (ii) respond as promptly as reasonably possible to any comments received from the SEC with respect to the Registration Statement or any amendment thereto;
- (iii) prepare and file with the SEC such amendments and supplements to such Registration Statement and the prospectus used in connection therewith as may be necessary to keep such Registration Statement continuously effective and free from any material misstatement or omission to state a material fact therein;
- (iv) furnish to Purchaser such number of copies of prospectuses in conformity with the requirements of the Securities Act and such other documents as the Purchaser may reasonably request, in order to facilitate the public sale or other disposition of all or any of the Registrable Shares by the Purchaser;

(v)	file such documents as may be required of the Company for
normal securities law clearance for the resale of the Registra	ble Shares in such states of the United States as may be reasonably
requested by the Purchaser and use its reasonable best efforts	s to maintain such blue sky qualifications during the period the
Company is required to maintain effectiveness of the Registr	ration Statement; <i>provided</i> , <i>however</i> , that the Company shall not be
required to qualify as a foreign corporation or execute a general consent to service of process in any jurisdiction in which it is not	
now so qualified or has not so consented;	

**(vi)** upon notification by the SEC that the Registration Statement has been declared effective by the SEC, the Company shall file the final prospectus under Rule 424 of the Securities Act;

**(vii)** advise the Purchaser promptly:

of the effectiveness of the Registration Statement or any post-effective amendments thereto;

(2) of any request by the SEC for amendments to the Registration Statement or amendments to the prospectus or for additional information relating thereto;

(3) of the issuance by the SEC of any stop order suspending the effectiveness of the Registration Statement under the Securities Act or of the suspension by any state securities commission of the qualification of the Registrable Shares for offering or sale in any jurisdiction, or the initiation of any proceeding for any of the preceding purposes; and

of the existence of any fact and the happening of any event that makes any statement of a material fact made in the Registration Statement, the prospectus and amendment or supplement thereto, or any document incorporated by reference therein, untrue, or that requires the making of any additions to or changes in the Registration Statement or the prospectus in order to make the statements therein not misleading;

**(viii)** use its reasonable best efforts to cause all Registrable Shares to be listed on each securities exchange, if any, on which equity securities of the Company are then listed; and

(ix) bear all expenses in connection with the procedures in paragraphs (i) through (viii) of this Section 7.7(a) and the registration of the Registrable Shares on such Registration Statement and the satisfaction of the blue sky laws of such states.

**Piggy-Back Registrations**. If, at any time after the date that is eighteen (18) months following the Effective Date, there is not an effective Registration Statement covering all of the Registrable Shares and the Company shall determine to prepare and file with the SEC a registration statement relating to an offering for its own account or the account of others under the Securities Act of any of its equity securities, other than on Form S-4 or Form S-8 (each as promulgated under the Securities Act) or their then equivalents relating to equity securities to be issued solely in connection with any acquisition of any entity or business or to equity securities issuable in connection with stock option or other employee benefit plans, then the Company shall send to the Purchaser, if the Purchaser is not then eligible to sell all of its Registrable Shares under Rule 144 in a three-month period, written notice of such determination and if, within ten (10) days after receipt of such notice, the Purchaser shall so request in writing, the Company shall include in such registration statement all or any part of such Registrable Shares that the Purchaser requests to be registered. Notwithstanding the foregoing, in the event that, in connection with any underwritten public offering, the managing underwriter(s) thereof shall impose a limitation on the number of shares of Common Stock which may be included in the registration statement because, in such underwriter(s)' judgment, marketing or other factors dictate such limitation is necessary to facilitate public distribution, then the Company shall be obligated to include in such registration statement only such limited portion of the Registrable Shares with respect to which the Purchaser has requested inclusion hereunder as the underwriter shall permit; provided, however, that (i) the Company shall not exclude any Registrable Shares unless the Company has first excluded all outstanding securities for which the holders are not contractually entitled to inclusion of such securities in such registration statement or are not contractually entitled to pro rata inclusion of such securities with the Registrable Shares and (ii) after giving effect to the immediately preceding proviso, any such exclusion of Registrable

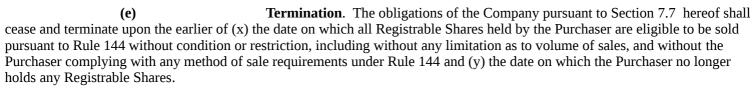
Shares shall be made pro rata among the Purchaser seeking to include Registrable Shares and the holders of other securities having the contractual right to inclusion of their securities in such registration statement, in proportion to the number of Registrable Shares and other securities, as applicable, sought to be included by each of the Purchaser and such holders. For the sake of clarity, the filing of a prospectus supplement or an amendment to the prospectus dated November 21, 2018 contained in the Company's registration statement on Form S-3/ASR (File No. 333-228513) shall not be deemed a filing of a registration statement relating to an offering for the Company's own account or the account of others under the Securities Act of any of its equity securities under the first sentence of this Section 7.7(b).

(c) Indemnification.

Company (and each person, if any, who controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, each officer of the Company and each director of the Company), from and against any losses, claims, damages or liabilities to which the Company (or any such officers, directors or controlling persons) may become subject (under the Securities Act or otherwise), insofar as such losses, claims, damages or liabilities (or actions or proceedings in respect thereof) arise out of, or are based upon, any material breach of this Section 7.7 by the Purchaser or any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement or any omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading in each case, on the effective date thereof, if, and to the extent, such untrue statement or omission or alleged untrue statement or omission was made in reliance upon and in conformity with written information furnished by or on behalf of the Purchaser specifically for use in preparation of the Registration Statement, and the Purchaser will reimburse the Company (and each of its officers, directors and controlling persons) for any legal or other expenses reasonably incurred in investigating, defending or preparing to defend any such action, proceeding or claim.

(ii) The Company agrees to indemnify and hold harmless the Purchaser (and each of the Purchaser's controlling persons, officers and directors) from and against any losses, claims, damages or liabilities to which the Purchaser (or any such controlling persons, officers or directors) may become subject (under the Securities Act or otherwise), insofar as such losses, claims, damages or liabilities (or actions or proceedings in respect thereof) arise out of, or are based upon, any material breach of this Section 7.7 by the Company or any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement or any omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading in each case, on the effective date thereof, unless, and to the extent, such untrue statement or omission or alleged untrue statement or omission was made in reliance upon and in conformity with written information furnished by or on behalf of the Purchaser specifically for use in preparation of the Registration Statement, and the Company will reimburse the Purchaser (and each of its controlling persons, officers, and directors) for any legal or other expenses reasonably incurred in investigating, defending or preparing to defend any such action, proceeding or claim.

(d) Prospectus Delivery. The Purchaser acknowledges that there may be times when the Company must suspend the use of the prospectus forming a part of the Registration Statement until such time as an amendment to the Registration Statement has been filed by the Company and declared effective by the SEC, or until such time as the Company has filed an appropriate report with the SEC pursuant to the Exchange Act. The Purchaser hereby covenants that it will not sell any Registrable Shares pursuant to said prospectus during the period commencing at the time at which the Company gives the Purchaser notice of the suspension of the use of said prospectus and ending at the time the Company gives the Purchaser may thereafter effect sales pursuant to said prospectus.



- **(f) Information Rights.** With a view to making available to the Purchaser the benefits of Rule 144, and any other rule or regulation of the SEC that may at any time permit the Purchaser to sell securities of the Company to the public without registration or pursuant to a registration statement on Form S-1 or Form S-3, for so long as the Company is subject to the public reporting requirements of the Exchange Act, the Company shall, until such time as all Registrable Shares may be sold by the Purchaser without condition or restriction pursuant to Rule 144, including without any limitation as to volume of sales, and without the Purchaser complying with any method of sale requirements under Rule 144:
- (i) make and keep available adequate current public information, as those terms are understood and defined in Rule 144;
- (ii) use its reasonable best efforts to file with the SEC in a timely manner all reports and other documents required of the Company under the Exchange Act; and
- (iii) furnish to the Purchaser, so long as the Purchaser owns any Registrable Shares, upon reasonable request by the Purchaser: (x) to the extent accurate, a written statement by the Company that it has complied with the reporting requirements of Rule 144 and the Exchange Act; and (y) such other information as may be reasonably requested in availing the Purchaser of any rule or regulation of the SEC that permits the selling of any such securities without registration or pursuant to Form S-3.

Notwithstanding anything set forth in this Agreement to the contrary, the Company shall not be required to disclose material non-public information pursuant to this Agreement to Purchaser unless mutually agreed upon by the parties, and shall reasonably cooperate with procedures established by the Purchaser to limit the disclosure to Purchaser of any such material non-public information to only those specific individuals designated in writing by either the Purchaser or the Company, in each case acting reasonably.

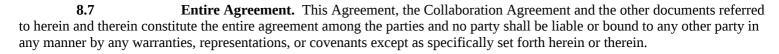
#### 8. MISCELLANEOUS.

- **8.1 Termination**. This Agreement may be terminated by the Purchaser, as to such Purchaser's obligations hereunder only, by written notice to the Company, if the Closing has not been consummated on or before April 10, 2020; provided, however, that nothing contained in this Section 8.1 shall relieve any party from liability for fraud or any intentional or willful breach of this Agreement.
- **8.2 Waivers and Amendments.** Any term of this Agreement may be amended and the observance of any term of this Agreement may be waived (either generally or in a particular instance and either retroactively or prospectively), only with the written consent of both the Company and the Purchaser.
- **8.3 Severability.** If one or more provisions of this Agreement are held to be unenforceable under applicable law, such provision(s) shall be excluded from this Agreement and the balance of the Agreement shall be interpreted as if such provision(s) were so excluded and shall be enforceable in accordance with its terms.
- **8.4 Governing Law; Submission to Jurisdiction.** This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware, without regard to conflicts of law principles that would require the application of the Law of any other jurisdiction. Any action brought, arising out of, or relating to this Agreement shall be brought in the Court of Chancery of the State of Delaware. Each party hereby irrevocably submits to the exclusive jurisdiction of said Court in respect of any claim relating to the validity, interpretation and enforcement of this Agreement, and hereby waives, and agrees not to assert, as a defense in any action, suit or proceeding in which any such claim is made that it is not subject thereto or

that such action, suit or proceeding may not be brought or is not maintainable in such courts, or that the venue thereof may not be appropriate or that this agreement may not be enforced in or by such courts. The parties hereby consent to and grant the Court of Chancery of the State of Delaware jurisdiction over such parties and over the subject matter of any such claim and agree that mailing of process or other papers in connection with any such action, suit or proceeding in the manner provided in Section 8.10 or in such other manner as may be permitted by law, shall be valid and sufficient thereof.

- **8.5 Counterparts.** This Agreement may be executed in two or more counterparts, each of which shall be deemed an original document, and all of which, together with this writing, shall be deemed one instrument. Facsimile and electronic (PDF) signatures shall be as effective as original signatures.
- **8.6 Successors and Assigns.** Except as expressly provided hereunder, neither this Agreement nor any rights or obligations hereunder may be assigned or otherwise transferred by either party without the prior written consent of the other party; *provided*, *however*, that either party may assign this Agreement and its rights and obligations hereunder without the other party's consent in connection with the transfer or sale of all or substantially all of the business of such party to which the Collaboration Agreement relates to a third party, whether by merger, sale of stock, sale of assets or otherwise, provided that upon the consummation by the Company of any such merger, sale of stock, sale of assets or other similar transaction, the obligations of the Purchaser under Section 7.1 shall terminate. Notwithstanding the foregoing, the Purchaser may assign any or all of its rights under this Agreement to an Affiliate, provided that the assigning party shall remain liable and responsible to the non-assigning party hereto for the performance and observance of all such duties and obligations by such Affiliate.

The rights and obligations of the parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the parties. Any assignment not in accordance with this Agreement shall be void.



- **8.8 Payment of Fees and Expenses.** Each of the Company and the Purchaser shall bear its own expenses and legal fees incurred on its behalf with respect to this Agreement and the transactions contemplated hereby; provided, that upon the Closing, the Company shall pay the reasonable fees and expenses of counsel for the Purchaser in connection with the preparation and negotiation of this Agreement and the consummation of the transactions contemplated hereby, in an amount not to exceed \$50,000 in the aggregate. If any action at law or in equity is necessary to enforce or interpret the terms of this Agreement, the prevailing party shall be entitled to reasonable attorney's fees, costs and necessary disbursements in addition to any other relief to which such party may be entitled.
- **8.9 Broker's Fee.** Each of the Company and the Purchaser hereby represents that there are no brokers or finders entitled to compensation in connection with the sale of the Shares, and each party shall indemnify the other party for any such fees for which such party is responsible.
- **8.10 Notices.** Any notice required or permitted to be given by this Agreement shall be in writing and in English and shall be (a) delivered by hand or overnight courier with tracking capabilities or (b) mailed postage prepaid by first class, registered or certified mail addressed as set forth below unless changed by notice so given:

If to the Purchaser:

[\*\*\*]

with a copy (which shall not constitute notice) to:

[\*\*\*]

with a further copy (which shall not constitute notice) to:

[\*\*\*]

# If to the Company:

Fate Therapeutics, Inc. 3535 General Atomics Court Suite 200 San Diego, California, 92121 Attention: Chief Executive Officer E-Mail: [\*\*\*]

and

Fate Therapeutics, Inc. 3535 General Atomics Court Suite 200 San Diego, California, 92121 Attention: Office of the General Counsel

E-Mail: [\*\*\*]

Any such notice shall be deemed given (i) on the date received if delivered in accordance with Section 8.10(a), or (ii) five (5) Business Days after mailing if mailed in accordance with Section 8.10(b). 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 Party's notices in accordance with this Section 8.10. It is understood and agreed that this Section 8.10 does not intend to govern day-today business communications necessary between the Parties in performing their duties under the terms of the Collaboration Agreement.

**8.11 Securities Laws Disclosure; Publicity.** The Company shall file a Current Report on Form 8-K, including this Agreement as an exhibit thereto or to the Company's Quarterly Report on Form 10-Q or Annual Report on Form 10-K covering the quarterly period in which this Agreement becomes effective, with the SEC within the time required by the Exchange Act, each of which must be agreed to by both parties or one of their respective Affiliates. The Company and the Purchaser, or any of their respective Affiliates, shall consult with each other in issuing any press releases with respect to the transactions contemplated hereby and neither the Company nor the Purchaser shall issue any such press release nor otherwise make any such public statement without the prior consent of the Company, with respect to any press release of the Purchaser, or without the prior consent of the Purchaser, with respect to any press release of the Company, which consent shall not unreasonably be withheld or delayed, except if such disclosure is required by law, in which case the Company shall allow the Purchaser or an

Affiliate of the Purchaser, to the extent reasonably practicable in the circumstances, reasonable time to comment on such release or announcement in advance of such issuance. The Company shall not publicly disclose the name of the Purchaser or an Affiliate of the Purchaser, or include the name of the Purchaser or an Affiliate of the Purchaser in any press release or filing with the SEC or any regulatory agency or Nasdaq, without the prior written consent of the Purchaser or an Affiliate of Purchaser, except (a) as required by federal securities law in connection with (i) any registration statement contemplated by the registration rights agreement herein or (ii) the filing of a Current Report on Form 8-K, or Company's Quarterly Report on Form 10-Q or Annual Report on Form 10-K, or this Agreement (including signature pages thereto) with the SEC, (b) to the extent such disclosure is required by law, request of the staff of the SEC or Nasdaq regulations, in which case the party that is required to make such disclosure shall provide the other party (or, in the event that Purchaser is such other party, an Affiliate of Purchaser) with prior written notice of such disclosure permitted under this subclause (b), or (c) the information is already in the public domain through no breach of this Section 8.11.

- **8.12 Headings.** The headings of the various sections of this Agreement have been inserted for convenience of reference only and shall not be deemed to be part of this Agreement.
- **8.13 Disclaimer**. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT AND THE COLLABORATION AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY TO THE OTHER PARTY OF ANY NATURE, EXPRESS OR IMPLIED.
- **8.14 Limitation of Liability**. NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT.

[SIGNATURE PAGE TO FOLLOW]

**IN WITNESS WHEREOF**, the parties hereto have caused this Stock Purchase Agreement to be executed by their duly authorized representatives as of the day and year first above written.

FATE THERAPEUTICS, INC.

By: /s/ J. Scott Wolchko

Name: J. Scott Wolchko

Title: President and Chief Executive Officer

JOHNSON & JOHNSON INNOVATION – JJDC, INC.

By: /s/ Asish K. Xavier

Name: Asish K. Xavier

Title: VP, Venture Investments

[SIGNATURE PAGE TO STOCK PURCHASE AGREEMENT]

# Schedule 3.8

On or before the date on which the Company publicly discloses its entry into the Collaboration Agreement and this Agreement, the Company intends to file a Current Report on Form 8-K containing the following disclosure under Item 8.01 of Form 8-K:

"[T]he Company is supplementing the risk factors previously disclosed in its Annual Report on Form 10-K for the year ended December 31, 2019 with the addition of the following risk factor under the subsection "Risks Related to Our Business and Industry":

The outbreak of the novel strain of coronavirus, SARS-CoV-2, which causes COVID-19, could adversely impact our business, including our clinical trials and preclinical studies.

The outbreak of the novel coronavirus, SARS-CoV-2, which causes coronavirus disease 2019 (COVID-19), has evolved into a global pandemic. The coronavirus has spread to many regions of the world, including the United States and Europe. As a result of the coronavirus pandemic, we may experience disruptions that could materially impact our business. The extent to which the coronavirus impacts our business and operating results will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning the coronavirus and the actions taken to contain the coronavirus or treat its impact, among others.

As a result of the COVID-19 pandemic, various aspects of our business operations have been, and could continue to be, disrupted. In response to the pandemic, we have implemented a work from home policy, with our administrative employees continuing their work outside of our offices, and restricted on-site staff to only those required to execute certain laboratory, manufacturing and related support activities. The increase in working remotely could increase our cyber security risk, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business operations or delay necessary interactions with local and federal regulators, ethics committees, manufacturing sites, and clinical trial sites. In addition, as a result of shelter-in-place orders or other mandated travel restrictions, our on-site staff conducting research and development, preclinical studies, and manufacturing activities may not be able to access our laboratories or manufacturing space, and these core activities may be significantly limited or curtailed, possibly for an extended period of time.

In addition, our ongoing and planned clinical trials have been and will likely continue to be affected by the pandemic. Study procedures (particularly any procedures that may be deemed non-essential), site initiation, participant recruitment and enrollment, participant dosing, shipment of our product candidates, distribution of clinical trial materials, study monitoring, site inspections and data analysis may be paused or delayed due to changes in hospital or research institution policies, federal, state or local regulations, prioritization of hospital and other medical resources toward pandemic efforts, or other reasons related to the pandemic. If the coronavirus continues to spread, some participants and clinical investigators may not be able to comply with clinical trial protocols. For example, quarantines or other travel limitations (whether voluntary or required) may impede participant movement, affect access to study sites, or interrupt healthcare services, and we may be unable to conduct our clinical trials. Furthermore, the pandemic could result in interruption or delays in the operations of the U.S. Food and Drug Administration and other regulatory agencies. The extent and impact of such disruptions are currently unpredictable. Any prolongation or de-prioritization of our clinical trials or delay in regulatory review resulting from such disruptions could materially affect the development and study of our product candidates.

Our research, preclinical development, and manufacturing operations also may be adversely impacted by the COVID-19 pandemic. We currently utilize third parties to, among other things, supply and manufacture raw materials, components, consumables, and our product candidates, to ship our product candidates and manufacturing materials, and to perform certain testing relating to our product candidates. We also manufacture our product candidates and perform various related testing at our manufacturing facility, and conduct research and development activities. If we, or any third parties in our supply chain for materials which are used in either the manufacture of our product candidates or the conduct of our research and development, are adversely impacted by restrictions resulting from the coronavirus outbreak, our supply chain may be disrupted and our ability to manufacture and ship our product candidates for our clinical trials and to conduct research and development activities may be limited.

In addition, the trading prices for our common stock and other biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through equity or debt financings, or such financing transactions may be on unfavorable terms. While the potential economic impact brought by and the duration of the pandemic may be difficult to assess or predict, it has already caused, and is likely to result in further, significant disruption of global financial markets, which may reduce our ability to access capital either at all or on favorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the spread of COVID-19 could materially and adversely affect our business and the value of our common stock.

The ultimate impact of the current pandemic, or any other health epidemic, is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical and preclinical programs, our clinical, preclinical, research, manufacturing, and regulatory activities, healthcare systems or the global economy as a whole. However, these effects could have a material adverse impact on our operations, and we will continue to monitor the situation closely."

#### STOCK PURCHASE AGREEMENT

This Stock Purchase Agreement (this "*Agreement*") is made as of June 8, 2020 (the "*Effective Date*"), by and between Fate Therapeutics, Inc., a Delaware corporation (the "*Company*"), having its principal place of business at 3535 General Atomics Court, Suite 200, San Diego, CA 92121, and Johnson & Johnson Innovation – JJDC, Inc., a New Jersey corporation (the "*Purchaser*"), having its principal place of business at 410 George Street, New Brunswick, New Jersey 08901.

**W**HEREAS, the Company and Janssen Biotech, Inc., an Affiliate of the Purchaser, previously entered into that certain Collaboration and Option Agreement, dated as of April 2, 2020 (the "*Collaboration Agreement*");

**W**HEREAS, the Company and Purchaser previously entered into that certain Stock Purchase Agreement, dated as of April 2, 2020 (the "*Existing Agreement*");

Whereas, Section 7.1(a) of the Existing Agreement provides that in the event that the Company consummates, on or before the date twelve (12) months after the Closing Date (as defined in the Existing Agreement), an underwritten public offering of shares of the Company's common stock, par value \$0.001 per share ("Common Stock") pursuant to an effective registration statement under the Securities Act that would result in aggregate gross proceeds (together with the proceeds from any shares of Common Stock sold pursuant to this Agreement) to the Company of at least \$150,000,000 (a "Follow-On Offering"), the Company shall have the right (the "Company Participation Right"), but not the obligation, to require that the Purchaser purchase, in a concurrent private placement exempt from the registration requirements of the Securities Act, an aggregate of \$50,000,000 of the Company's Common Stock (the "Participation Right Shares") on the same terms and at a price per share equal to the price at which the Common Stock is issued and sold to the public in the Follow-On Offering at a closing to be held concurrently with the closing of the Follow-On Offering (as such closing may be delayed pursuant to Section 7.1(b)(ii) of the Existing Agreement);

1

[\*\*\*] Certain information in this exhibit has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the registrant if publicly disclosed.

WHEREAS, the Company has exercised the Company Participation Right; and

**W**HEREAS, the Company wishes to sell to the Purchaser, and the Purchaser wishes to purchase from the Company, the Participation Right Shares, on the terms and subject to the conditions set forth in this Agreement.

#### AGREEMENT

In consideration of the mutual covenants contained in this Agreement, and for other good and valuable consideration, the receipt of which is hereby acknowledged, the Company and the Purchaser hereby agree as follows:

#### 1. **D**EFINITIONS

Capitalized terms used but not defined herein shall have the meanings provided in the Collaboration Agreement. In addition, the following terms shall have the respective meanings set forth below:

- 1.1 "Affiliate" shall mean any Person that directly or indirectly is controlled by, controls or is under common control with either Company or Purchaser, as applicable, at the time the determination of affiliation is being made. For the purposes of this definition, 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 ownership of more than fifty percent (50%) of the voting securities, capital stock or equity interests of such Person or (b) possession, directly or indirectly, of the power to direct the management and policies of such Person, as applicable, whether through the ownership or control of voting securities, by contract or otherwise.
- **1.2** "*Aggregate Purchase Price*" shall mean the product of the Share Price multiplied by the number of Shares, rounded up to the nearest whole penny.

- **1.3** "Antitrust Filings" shall mean any premerger notification and report forms required under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, including the rules and regulations thereunder, and any similar filings required under foreign antitrust or competition laws and regulations in connection with the exercise of the Company Participation Right and the issuance of the Shares under this Agreement.
- **1.4** "*Business Day*" means a day other than Saturday, Sunday or any day on which commercial banks located in New York, New York are authorized or obligated by Laws to close.
  - **1.5** *"Closing"* shall have the meaning set forth in Section 2.3(a).
  - **1.6** *"Closing Date"* shall have the meaning set forth in Section 2.3(a).
- **1.7** "*Exchange Act*" shall mean the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.
- **1.8** "*Governmental Authority*" shall mean any court, agency, authority, department, regulatory body or other instrumentality of any government or country or of any national, federal, state, provincial, regional, country, city or other political subdivision of any such government or country or any supranational organization of which any such country is a member.
- **1.9** "*Intellectual Property*" shall mean trademarks, trade names, trade dress, service marks, copyrights, and similar rights (including registrations and applications to register or renew the registration of any of the foregoing), patents and patent applications, trade secrets, and any other similar intellectual property rights.
- **1.10** *"Intellectual Property License"* shall mean any license, permit, authorization, approval, contract or consent granted, issued by or with any Person relating to the use of Intellectual Property.
- **1.11** "*Law*" or "*Laws*" shall mean all laws, statutes, rules, regulations, orders, judgments, injunctions and/or ordinances of any Governmental Authority.
  - **1.12** "*Nasdaq*" shall mean The Nasdaq Stock Market LLC.

- **1.13** "*Person*" shall mean any individual, corporation, limited liability company, partnership, association, trust, estate or other entity or organization.
  - **1.14** "*Rule 144*" shall have the meaning set forth in Section 4.8(a).
  - **1.15** "SEC" shall mean the U.S. Securities and Exchange Commission.
- **1.16** "SEC Filings" shall mean all reports, schedules, forms, statements and other documents filed or required to be filed by the Company with the SEC pursuant to the requirements of the Securities Act or the Exchange Act, including material filed pursuant to Section 13(a) or 15(c) of the Exchange Act, in each case, together with all exhibits, supplements, amendments and schedules thereto, and all documents incorporated by reference therein.
- **1.17** "*Securities Act*" shall mean the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.
  - **1.18** "*Shares*" shall have the meaning set forth in Section 2.3(a).
  - **1.19** *"Share Price"* shall mean \$28.31 per share of Common Stock.

#### 2. AGREEMENT TO SELL AND PURCHASE

- **2.1 Authorization of Shares.** The Company has authorized the sale and issuance to the Purchaser of the Shares under the terms and conditions of this Agreement.
- **2.2 Sale and Issuance of Shares.** On the basis of the representations and warranties herein, and upon the terms and subject to the conditions hereof, the Purchaser agrees to purchase from the Company, and the Company agrees to issue and sell to the Purchaser, the Shares at a price per share equal to the Share Price.

# 2.3 Closing.

**(a) Closing.** Subject to the satisfaction or waiver of the conditions set forth herein, the closing of the purchase and sale of the Shares (the "*Closing*") shall take place on the later of (i) the date of the closing of the Firm Shares (as defined below) sold in the Follow-On Offering and (ii) within the three Business Days following the early termination or expiration of

any applicable waiting period(s) relating to the Antitrust Filings (the date of the Closing, the "Closing Date"), at the offices of the Company. At the Closing, (i) the Company shall deposit 1,766,160 shares of Common Stock (or, in the event such number of shares, when aggregated with any shares of Common Stock then held by Purchaser and/or its Affiliates, would result in the Purchaser, together with its Affiliates, beneficially owning in excess of 14.999% of the Company's total outstanding shares of Common Stock or the voting power of the Company immediately after the Closing, such lesser whole number of shares as would be equal to the maximum number that could be issued without causing such ownership of Purchaser and/or its Affiliates to exceed 14.999% of the Company's total outstanding shares of Common Stock immediately after the Closing) (the "Shares") with its transfer agent to be held in book entry form for the benefit of, and in the name of, the Purchaser and (ii) the Purchaser shall pay the Aggregate Purchase Price for the Shares in U.S. dollars by bank wire transfer in immediately available funds to a bank account designated by the Company. In the event of any stock dividend, stock split, combination of shares, recapitalization or other similar change in the capital structure of the Company after the date hereof and on or prior to the Closing Date that affects or relates to the Common Stock, the number of Shares and the Share Price shall be adjusted proportionately.

# 3. Representations, Warranties and Covenants of the Company

The Company hereby represents and warrants to the Purchaser as follows:

- **3.1 Organization, Good Standing and Qualification**. The Company is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware and has all requisite corporate power and authority to carry on its business. The Company is duly qualified to transact business as a corporation and is in good standing in each jurisdiction in which the failure so to qualify would have a material adverse effect upon the Company's ability to perform its obligations under this Agreement.
- **3.2 Authorization; Due Execution.** The Company has the requisite corporate power and authority to enter into this Agreement and to perform its obligations under the terms of this Agreement. All corporate action on the part of the Company, its officers, directors and stockholders necessary for the authorization, execution and delivery of this Agreement has been

taken. This Agreement has been duly authorized, executed and delivered by the Company and, upon due execution and delivery by the Purchaser, this Agreement will be a valid and binding obligation of the Company, enforceable in accordance with its terms, except as enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally or by equitable principles.

# 3.3 Capitalization and Voting Rights.

The capitalization of the Company is as set forth in the SEC Filings. The authorized capital stock of the Company consists of 150,000,000 shares of Common Stock and 5,000,000 shares of preferred stock, par value \$0.001 per share, of the Company ("Preferred Stock"). As of the date hereof, 2,819,549 shares of Preferred Stock are designated as Class A Convertible Preferred Stock, of which 2,794,549 shares are issued and outstanding, and there are 77,772,238 shares of Common Stock issued and outstanding, of which no shares are owned by the Company. There are no other shares of any other class or series of capital stock of the Company issued and outstanding. All of the issued and outstanding shares of Common Stock have been duly authorized and validly issued and are fully paid and non-assessable. The Company has no capital stock reserved for issuance, except that, as of June 8, 2020, there are (i) 13,972,745 shares of Common Stock reserved for issuance upon the conversion of the Class A Convertible Preferred Stock, (ii) 12,011,457 shares of Common Stock reserved for issuance upon exercise of outstanding options and vesting of outstanding restricted stock units granted under the Company's 2007 Equity Incentive Plan, Amended and Restated 2013 Stock Option and Incentive Plan and Inducement Equity Plan (collectively, the "Equity Plans"), (iii) 4,066,656 shares of Common Stock available for future grant under the Equity Plans, (iv) 729,000 shares of Common Stock available for issuance under the Company's 2013 Employee Stock Purchase Plan and (v) zero shares of Common Stock reserved for issuance upon exercise of warrants outstanding. Except as stated above or in the SEC Filings, the Company is not obligated to (x) issue any additional options, warrants, calls, subscriptions or other rights to acquire shares of capital stock of, or other equity interests in, the Company or (y) redeem, purchase, repurchase or otherwise acquire or cause to be acquired any capital stock of, or other equity interests in, the Company. The issuance of the Shares pursuant to this Agreement will not give rise to any preemptive rights or rights of first refusal on behalf of any third party. All of the authorized shares of Common Stock are entitled to one vote per share.

- (b) As of the date hereof, except as disclosed in the SEC Filings, there are not any restrictions on the transfer of capital stock of the Company other than pursuant to state and federal securities Laws.
- (c) The Company is not a party to or subject to any agreement or understanding relating to the voting of shares of capital stock of the Company or the giving of written consents by a stockholder or director of the Company.
- (d) The 6,181,562 shares of Common Stock to be sold in the Follow-On Offering (the "*Firm Shares*") and the up to 927,234 additional shares to be sold pursuant to an option provided to the underwriters (the "*Option Shares*," and together with the Firm Shares, the "*Follow-On Shares*") have been duly authorized and, when issued, delivered and paid for in accordance with that certain Underwriting Agreement, dated as of June 8, 2020, by and between the Company and Jefferies LLC and SVB Leerink LLC, as representatives of the several underwriters listed on Schedule A thereto, will be validly issued, fully paid and nonassessable. The Company has prepared and filed with the SEC a shelf registration statement on Form S-3, File No. 333-228513, including a base prospectus and the preliminary prospectus supplement dated June 8, 2020, and shall file the final prospectus supplement dated June 8, 2020 within the time periods required by applicable rules and regulations of the SEC, all effective under the Securities Act and to be used in connection with the public offering and sale of the Follow-On Shares.
- **3.4 Subsidiaries**. The Company has disclosed all of its subsidiaries required to be disclosed pursuant to Item 601(b)(21) of Regulation S-K in an exhibit to its Annual Report on Form 10-K (the "*Subsidiaries*" and each, a "*Subsidiary*"). Each Subsidiary (i) has been duly organized and is validly existing in good standing under the laws of the jurisdiction of its incorporation or organization, has corporate or similar power and authority to own, lease and operate its properties and to conduct its business as presently conducted, and (ii) is duly qualified to transact business and is in good standing in each jurisdiction in which such qualification is required, whether by reason of the ownership or leasing of property or the conduct of business, except where the failure to be so organized, existing or qualified would not, individually or in the aggregate, have a material adverse effect on the Company's ability to perform its obligations under this Agreement. All of the issued and outstanding capital stock of each Subsidiary has been duly authorized and validly issued, is fully paid and nonassessable and is owned by the Company, directly or through its Subsidiaries, and is free and clear of any security interest, mortgage, pledge, lien, encumbrance, claim or equity.

- **3.5 Valid Issuance of Stock.** The Shares, when issued, sold and delivered in accordance with the terms of Section 2 hereof for the consideration and on the terms and conditions set forth herein, will be duly and validly authorized and issued, fully paid and nonassessable and, based in part upon the representations of the Purchaser in this Agreement, will be issued in compliance with all applicable federal and state securities laws.
- **3.6 No Defaults.** There exists no default under the provisions of any instrument or agreement evidencing, governing or otherwise relating to any material indebtedness of the Company or any of its Subsidiaries. There exists no default under any other agreement to which the Company or any of its Subsidiaries is a party, which default would have a material adverse effect upon the Company's ability to perform its obligations under this Agreement.
- 3.7 **SEC Filings; Financial Statements.** Since January 1, 2017, the Company has timely filed with the SEC all SEC Filings. Such SEC Filings were prepared in accordance with and, as of the date on which each such SEC Filing was filed with the SEC, complied in all material respects with the applicable requirements of the Securities Act and Exchange Act. None of such SEC Filings, including, without limitation, any financial statements, exhibits and schedules included therein and documents incorporated therein by reference, at the time filed, declared effective or mailed, as the case may be, contained an untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading. The consolidated financial statements of the Company and its Subsidiaries included in its Annual Report on Form 10-K for the fiscal year ended December 31, 2019 comply as to form in all material respects with applicable accounting requirements and the published rules and regulations of the SEC with respect thereto, have been prepared in accordance with United States generally accepted accounting principles ("GAAP") applied on a consistent basis during the periods involved (except as may be indicated in the notes thereto) and fairly present in all material respects the financial position of the Company as of the dates thereof and the results of its operations and cash flows for the periods then ended. Except (i) as set forth in the SEC Filings or (ii) for liabilities incurred in the ordinary course of business subsequent to the date of the most recent balance sheet contained in the SEC Filings, the Company has no liabilities, whether absolute or accrued, contingent or otherwise, other than those that would not,

individually or in the aggregate, have a material adverse effect on the business, operations or financial condition of the Company and its Subsidiaries, taken as a whole. There are no material unconsolidated Subsidiaries of the Company or any material off-balance sheet arrangements of any type (including any off balance sheet arrangements required to be disclosed pursuant to Item 303(a)(4) of Regulation S-K promulgated under the Securities Act) that have not been so described in the SEC Filings filed prior to the date hereof nor any obligations to enter into any such arrangements.

- 3.8 Material Changes. Since December 31, 2019, except as specifically disclosed in SEC Filings dated prior to the Effective Date: (i) there have been no events, occurrences or developments that have had or would reasonably be expected to have, either individually or in the aggregate, a material adverse effect on the business, operations or financial condition of the Company and its Subsidiaries, taken as a whole, (ii) the Company has not incurred any material liabilities (contingent or otherwise) other than (A) trade payables and accrued expenses incurred in the ordinary course of business consistent with past practice and (B) liabilities not required to be reflected in the Company's financial statements pursuant to GAAP or disclosed in filings made with the SEC, (iii) the Company has not altered materially its method of accounting or the manner in which it keeps its accounting books and records, (iv) the Company has not declared or made any dividend or distribution of cash, shares of capital stock or other property to its stockholders or purchased, redeemed or made any agreements to purchase or redeem any shares of its capital stock (other than in connection with repurchases of unvested stock issued to employees of the Company), and (v) the Company has not issued any equity securities, except Common Stock issued pursuant to existing Company equity incentive, stock option or stock purchase plans or agreements or executive and director compensation arrangements disclosed in the SEC Filings dated prior to the Effective Date.
- **3.9 Investment Company**. The Company is not, and immediately after receipt of payment for the Shares, will not be an "investment company" within the meaning of the Investment Company Act of 1940, as amended. The Company shall conduct its business in a manner so that it will not become subject to the Investment Company Act of 1940, as amended.

- **3.10 Registration Rights.** Other than as disclosed in the SEC Filings, no Person has any right to cause the Company to effect the registration under the Securities Act of the transfer of any securities of the Company.
- Listing and Maintenance Requirements. The Common Stock is registered pursuant to Section 12(b) of the Exchange Act, and the Company has taken no action designed to terminate the registration of the Common Stock under the Exchange Act nor has the Company received any notification that the SEC is contemplating terminating such registration. The Company has not, in the previous twelve (12) months, received (i) written notice from Nasdaq that the Company is not in compliance with the listing or maintenance requirements of Nasdaq that would result in immediate delisting or (ii) any notification, Staff Delisting Determination, or Public Reprimand Letter (as such terms are defined in applicable Nasdaq listing rules) that requires a public announcement by the Company of any noncompliance or deficiency with respect to such listing or maintenance requirements (other than any public announcement relating to noncompliance or deficiency under Rules 5605(b)(1), 5605(c)(2), 5450(a)(1), or 5250(c)(1) of the Nasdaq listing rules). The Company is in compliance with all listing and maintenance requirements of Nasdaq on the date hereof, except for any noncompliance or deficiency which may exist under Rules 5605(b)(1), 5605(c)(2), 5605(d)(2), 5450(a)(1), or 5250(c)(1) of the Nasdaq listing rules and in each such case where the Company fully expects to, and has a plan to, regain compliance in accordance with applicable Nasdaq procedures and cure periods such as to avoid any suspension of trading of the Company's Common Stock on Nasdaq or delisting actions by Nasdaq.
- **3.12 Private Placement**. Assuming the accuracy of Purchaser's representations and warranties set forth in Sections 4.4 4.7 hereof, the offer, sale and issuance of the Shares to be issued in conformity with the terms of this Agreement constitute transactions which are exempt from the registration requirements of the Securities Act and from all applicable state registration or qualification requirements. Neither the Company nor any Person acting on its behalf will take any action that would cause the loss of such exemption. The issuance and sale of the Shares hereunder does not contravene the rules and regulations of Nasdaq.

- **3.13 No Integrated Offering.** Assuming the accuracy of Purchaser's representations and warranties set forth in Sections 4.4 4.7 hereof, none of the Company nor, to the Company's knowledge, any of its Affiliates or any Person acting on its behalf has, directly or indirectly, at any time within the past six (6) months, made any offers or sales of any Company security or solicited any offers to buy any security under circumstances that would (i) eliminate the availability of the exemption from registration under Regulation D under the Securities Act in connection with the offer and sale by the Company of the Shares or (ii) other than with respect to the Existing Agreement Shares (as defined further below), cause the offering of the Shares to be integrated with prior offerings by the Company for purposes of any applicable law, regulation or stockholder approval provisions, including, without limitation, under the rules and regulations of Nasdaq.
- **3.14 OFAC**. Neither the Company nor, to the Company's knowledge, any director, officer, agent, employee, Affiliate or Person acting on behalf of the Company is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department ("**OFAC**"); and the Company will not directly or indirectly use the proceeds of the sale of the Shares, or lend, contribute or otherwise make available such proceeds to any Subsidiary, joint venture partner or other Person or entity, towards any sales or operations in Cuba, Iran, Syria, Sudan, Myanmar or any other country sanctioned by OFAC or for the purpose of unlawfully financing the activities of any Person that at the time of such financing is subject to any U.S. sanctions administered by OFAC.
- **3.15 FCPA**. Neither the Company nor, to the Company's knowledge, any agent or other Person acting on behalf of the Company, has: (i) directly or indirectly, used any funds for unlawful contributions, gifts, entertainment or other unlawful expenses related to foreign or domestic political activity, (ii) made any unlawful payment to foreign or domestic government officials or employees or to any foreign or domestic political parties or campaigns from corporate funds, (iii) failed to disclose fully any contribution made by the Company (or made by any Person acting on its behalf of which the Company is aware) which is in violation of law or (iv) violated in any material respect any provision of the Foreign Corrupt Practices Act of 1977, as amended.

- **3.16 Internal Accounting Controls**. The Company maintains a system of internal accounting controls sufficient to provide reasonable assurance that (i) transactions are executed in accordance with management's general or specific authorizations, (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain asset and liability accountability, (iii) access to assets or incurrence of liabilities is permitted only in accordance with management's general or specific authorization, and (iv) the recorded accountability for assets and liabilities is compared with the existing assets and liabilities at reasonable intervals and appropriate action is taken with respect to any differences.
- 3.17 Sarbanes-Oxley; Disclosure Controls. The Company is in compliance in all material respects with all of the provisions of the Sarbanes-Oxley Act of 2002, as amended, that are applicable to the Company. The Company has established disclosure controls and procedures (as such term is defined in Rule 13a-15(e) and 15d-15(e) under the Exchange Act) for the Company and designed such disclosure controls and procedures to ensure that information required to be disclosed by the Company in the reports 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. The Company's certifying officers have evaluated the effectiveness of the Company's disclosure controls and procedures as of the end of the period covered by the Company's most recently filed periodic report under the Exchange Act (such date, the "Evaluation Date"). The Company presented in its most recently filed periodic report under the Exchange Act the conclusions of the certifying officers about the effectiveness of the disclosure controls and procedures based on their evaluations as of the Evaluation Date. Since the Evaluation Date, there has been no change in the Company's internal control over financial reporting (as such term is defined in the Exchange Act) that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

- **3.18 Litigation**. No action, suit, investigation or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any of its Subsidiaries or any of its or their property or any officer or director of the Company in their capacity as such (collectively, "*Actions*"), is pending or, to the knowledge of the Company, threatened, which if adversely determined would have a material adverse effect on the Company and its Subsidiaries, whether or not arising from transactions in the ordinary course of business. There is no Action pending, or to the Company's best knowledge threatened, which if adversely determined could materially and adversely affect or challenge the legality, validity or enforceability of any of this Agreement or the Company's ability to consummate the transactions contemplated by this Agreement.
- **3.19 Licenses and Other Rights; Compliance with Laws**. The Company and each Subsidiary has all franchises, permits, licenses and other rights and privileges ("*Permits*") necessary to permit it to own its properties and to conduct its business as presently conducted and is in compliance thereunder, except where the failure to be in compliance does not and would not have a material adverse effect on the Company. The Company and each Subsidiary has not taken any action that would interfere with the Company's ability to renew all such Permit(s), except where the failure to renew such Permit(s) would not have a material adverse effect on the Company. The Company and each Subsidiary is and has been in compliance with all Laws applicable to its business, properties and assets, except where the failure to be in compliance does not and would not have a material adverse effect on the Company.
- **3.20 No Governmental Authority or Third Party Consents.** Other than in connection with the Antitrust Filings, no consent, approval, order or authorization of, or registration, qualification, designation, declaration or filing with, any federal, state, local or provincial Governmental Authority or other third party on the part of the Company or any of its Subsidiaries is required in connection with the authorization, execution and delivery by the Company of this Agreement, or with the authorization, issue and sale by the Company of the Shares, except for such notices required or permitted to be filed with certain state and federal securities commissions after the Closing Date, which notices will be filed on a timely basis.

- **3.21 No Conflict.** The Company's execution, delivery and performance of this Agreement, and compliance with the provisions hereof and thereof by the Company, do not and shall not: (a) violate any provision of applicable law or any ruling, writ, injunction, order, permit, judgment or decree applicable to the Company; (b) constitute a breach of, or default under (or an event which, with notice or lapse of time or both, would become a default under) or conflict with, or give rise to any right of termination, cancellation or acceleration of, any agreement, arrangement or instrument, whether written or oral, by which the Company or any of its assets are bound or (c) violate or conflict with any of the provisions of the Company's Amended and Restated Certificate of Incorporation or Amended and Restated Bylaws, each as amended to date, except, in the case of subsections (a) and (b), as would not have a material adverse effect on the Company.
- **3.22 Regulation M Compliance**. The Company has not, and to its knowledge no one acting on its behalf has, (i) taken, directly or indirectly, any action designed to cause or to result in the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of any of the Shares or (ii) sold, bid for, purchased, or paid any compensation for soliciting purchases of, any of the Shares.

# 3.23 Intellectual Property.

(a) The Intellectual Property that is owned by the Company or any Subsidiary is owned free from any liens or restrictions (other than any restrictions set forth in any Intellectual Property License relating to such Intellectual Property), and all of the Company's and its Subsidiaries material Intellectual Property Licenses are in full force and effect in accordance with their terms and are free of any liens or restrictions (other than any restrictions set forth in any such Intellectual Property Licenses), and neither the Company nor to the Company's knowledge any other party thereto, is in material breach of any such material Intellectual Property License, and no event has occurred that with notice or lapse of time or both would constitute such a breach or default thereunder or would result in the termination thereof or would cause or permit the acceleration or other change of any right or obligation of the loss of any benefit thereunder by the Company, except where any such failures to be in full force and effect, such liens or restrictions, such material breaches, and such events would not have a material

adverse effect on the Company. There is no material legal claim or demand of any Person pertaining to, or any proceeding which is pending (of which the Company has received notice or otherwise has knowledge) or, to the knowledge of the Company, threatened, (x) challenging the right of the Company in respect of any Company Intellectual Property, or (y) that claims that any default exists under any Intellectual Property License, except, in the case of (x) and (y) above, where any such claim, demand or proceeding would not have a material adverse effect on the Company.

- (b) (i) The Company or one of its Subsidiaries (x) owns, free and clear of any lien or encumbrance, (y) has a valid license to, or has an enforceable right, to use, as it is used or held for use, or (z) can acquire on commercially reasonable terms sufficient rights to, all valid U.S. and non-U.S. patents, trade secrets, know-how, trademarks, service marks, copyrights, and other proprietary and intellectual property rights, and all grants with respect to the foregoing (collectively, the "*Proprietary Rights*") known by the Company to be necessary for the conduct of the Company's business, the absence of which would not have or reasonably be expected to have a material adverse effect on the Company (such Proprietary Rights owned by or licensed to the Company collectively, the "*Company Rights*"); and (ii) the Company and its Subsidiaries has taken reasonable measures to protect the Company Rights, consistent with prudent commercial practices in the biotechnology industry, except where failure to take such measures would not have or reasonably be expected to have a material adverse effect on the Company.
- **3.24 Material Contracts**. Each franchise, contract or other document of a character required to be described in the SEC Filings or to be filed as an exhibit to the SEC Filings under the Securities Act and the rules and regulations promulgated thereunder (collectively, the "*Material Contracts*") is so described in all material respects or filed. The Company is in compliance with and not in default of its obligations under the Material Contracts, except where any such non-compliance or default would not have a material adverse effect on the Company.

- **Health Laws and FDA Compliance**. Except as would not, individually or in the aggregate, result in a 3.25 material adverse effect on the Company: (i) each of the Company and each of its Subsidiaries is and has been in compliance with statutes, laws, ordinances, rules and regulations applicable to the Company or its Subsidiaries for the ownership, testing, development, manufacture, packaging, processing, use, labeling, storage, or disposal of any product manufactured by or on behalf of the Company and its Subsidiaries or out-licensed by the Company and its Subsidiaries (each a "Company Product"), including without limitation, the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, et seq., and the Public Health Service Act, 42 U.S.C. § 262 (collectively, "Applicable Health Laws"); (ii) the Company and its Subsidiaries possess all licenses, certificates, approvals, authorizations, permits and supplements or amendments thereto required by any such Applicable Health Laws and/or for the ownership of their properties or the conduct of their business as it relates to a Company Product and as described in the SEC Filings (collectively, "Authorizations") and such Authorizations are valid and in full force and effect and neither the Company nor any of its Subsidiaries is in violation of any term of any such Authorizations; (iii) neither the Company nor any of its Subsidiaries has received any written notice of adverse finding, warning letter or other written correspondence or notice from the U.S. Food and Drug Administration (the "FDA") or any other Governmental Authority alleging or asserting noncompliance with any Applicable Health Laws or Authorizations relating to a Company Product; (iv) neither the Company nor any of its Subsidiaries has received written notice of any ongoing claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any Governmental Authority or third party alleging that any Company Product, operation or activity related to a Company Product is in violation of any Applicable Health Laws or Authorizations; and (v) neither the Company nor any of its Subsidiaries has received written notice that any Governmental Authority has taken, is taking or intends to take action to limit, suspend, modify or revoke any Authorizations.
- **3.26 Tests and Preclinical and Clinical Trials**. The studies, tests and preclinical and clinical trials conducted by or, to the Company's knowledge, on behalf of the Company that are described in the SEC Filings were and, if still pending, are being, conducted in all material respects in accordance with any applicable protocols submitted to the FDA or any Governmental Authority exercising comparable authority, procedures and controls pursuant to, where applicable, accepted professional and scientific standards, and all applicable Laws and

regulations; the descriptions of the studies, tests and preclinical and clinical trials conducted by or, to the Company's knowledge, on behalf of the Company, and the results thereof, contained in the SEC Filings are accurate and complete in all material respects; to the Company's knowledge, there are no subsequent studies, tests or preclinical and clinical trials, the results of which call into question in any material respect the results described in the SEC Filings; and the Company has not received any notices or correspondence from the FDA, any Governmental Authority exercising comparable authority or any Institutional Review Board requiring the termination, suspension, material modification or clinical hold of any studies, tests or preclinical or clinical trials currently being conducted by or on behalf of the Company.

- **3.27 Taxes.** (i) the Company and its Subsidiaries have filed all tax returns that are required to have been filed by each of them or has requested extensions of the filing date thereof and (ii) the Company and its Subsidiaries have paid all taxes required to be paid by any of them and any other assessment, fine or penalty levied against any of them, to the extent that any of the foregoing is due and payable, except in the case of clause (i) and (ii), for any such assessment, fine or penalty that is currently being contested in good faith or as would not have a material adverse effect on the Company, whether or not arising from transactions in the ordinary course of business and (iii) there are no tax audits ongoing of which the Company has received written notice.
- **3.28 Transfer Taxes**. There are no transfer taxes or other similar fees or charges under federal law or the laws of any state, or any political subdivision thereof, required to be paid in connection with the execution and delivery of this Agreement or the issuance or sale by the Company of the Shares.
- **3.29 Insurance**. The Company and its Subsidiaries are insured by insurers of recognized financial responsibility against such losses and risks and in such amounts as are reasonable and customary in the business in which it is engaged; all policies of insurance and fidelity or surety bonds insuring the Company and its Subsidiaries or their businesses, assets, employees, officers and directors are in full force and effect; the Company and its Subsidiaries are in compliance with the terms of such policies and instruments in all material respects; and there are no claims by the Company or any of its Subsidiaries under any such policy or instrument as to which any insurance company is denying liability or defending under a

reservation of rights clause; neither the Company nor any of its Subsidiaries has been refused any insurance coverage sought or applied for; and the Company has no reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business at a cost that would not have a material adverse effect on the Company, whether or not arising from transactions in the ordinary course of business.

- **3.30 Related Party Transactions**. No director or Affiliate of the Company, nor any family member of any officer, director or Affiliate of the Company has entered into any transaction with the Company or any of its Subsidiaries that would be required to be disclosed under Item 404 of Regulation S-K that has not been disclosed in the SEC Filings as required by the rules and regulations of the SEC.
- **3.31 Labor**. Neither the Company nor any of its Subsidiaries is bound by or subject to any collective bargaining agreement or any similar agreement with any organization representing its employees. No labor problem or dispute with the employees of the Company and its Subsidiaries exists or, to the knowledge of the Company, is threatened, and the Company is not aware of any existing or imminent labor disturbance by the employees of any of its principal suppliers or contractors, that would have a material adverse effect on the Company, whether or not arising from transactions in the ordinary course of business, except as contemplated in the SEC Filings.
- **3.32 Environmental Laws**. The Company and each of its Subsidiaries (i) is in compliance with any and all applicable foreign, federal, state and local laws and regulations relating to the protection of human health and safety, the environment or hazardous or toxic substances or wastes, pollutants or contaminants ("*Environmental Laws*"), (ii) has received and is in compliance with all permits, licenses or other approvals required of them under applicable Environmental Laws to conduct its business and (iii) has not received notice of any actual or potential liability under any environmental law, except where such non-compliance with Environmental Laws, failure to receive required permits, licenses or other approvals, or liability would not, individually or in the aggregate, have a material adverse effect on the Company, whether or not arising from transactions in the ordinary course of business. The Company has not been named as a "potentially responsible party" under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended.

- **3.33 No Disqualification Events.** With respect to the Shares to be offered and sold hereunder in reliance on Rule 506 under the Securities Act, none of the Company or any of its predecessors, and to the knowledge of the Company, any affiliated issuer, director, executive officer, other officer of the Company participating in the offering hereunder, beneficial owner of 20% or more of the Company's outstanding voting equity securities, calculated on the basis of voting power, nor any promoter (as that term is defined in Rule 405 under the Securities Act) connected with the Company in any capacity at the time of sale (each, an "*Issuer Covered Person*" and, together, "*Issuer Covered Persons*") is subject to any of the "Bad Actor" disqualifications described in Rule 506(d)(1)(i) to (viii) under the Securities Act (a "*Disqualification Event*"), except for a Disqualification Event covered by Rule 506(d)(2) or (d)(3). The Company has exercised reasonable care to determine whether any Issuer Covered Person is subject to a Disqualification Event. The Company has complied, to the extent applicable, with its disclosure obligations under Rule 506(e), and has furnished to the Purchaser a copy of any disclosures provided thereunder.
- **3.34 Other Covered Persons**. Except to attorneys for legal services, the Company is not aware of any person that has been or will be paid (directly or indirectly) remuneration in connection with the sale of any Regulation D Shares pursuant to this Agreement.
- **3.35 Shell Company**. As of the date hereof and the Closing Date, the Company is not a "shell company" nor a former "shell company" (as defined in Rule 405 of the Securities Act) and has never been a "shell company."
- **3.36 Application of Takeover Provisions.** The Company and the Company's Board of Directors have taken all necessary action in order to render inapplicable any control share acquisition, business combination, poison pill (including any distribution under a rights agreement) or other similar anti-takeover provision under the Company's Amended and Restated Certificate of Incorporation or the Laws of its state of incorporation that is or could become applicable to the Purchaser as a result of the Purchaser and the Company fulfilling their obligations or exercising their rights under this Agreement, including without limitation as a result of the Company's issuance of the Shares and the Purchaser's ownership of the Shares.

- **3.37 Passive Foreign Investment Company; Controlled Foreign Company**. Neither the Company nor its Subsidiaries will be deemed to constitute a "passive foreign investment company" within the meaning of 26 USC §1297(a) or a "controlled foreign company" within the meaning of 26 USC §957.
- **3.38 Full Disclosure**. The Company understands that the Purchaser will rely on the foregoing representations in effecting the purchase of the Shares. No representation or warranty of the Company in this Agreement, when taken together with the SEC Filings, contains any untrue statement of a material fact or omits to state any material fact necessary in order to make the statements contained herein or therein, in light of the circumstances under which they were made, not misleading.

#### 4. Representations, Warranties and Covenants of the Purchaser

The Purchaser hereby represents and warrants to the Company as of the Closing Date as follows:

- **4.1 Organization and Good Standing**. The Purchaser is a corporation duly organized, validly existing and in good standing under the laws of its jurisdiction of incorporation and has all requisite corporate power and authority to carry on its business.
- **4.2 Authorization; Due Execution.** The Purchaser has the requisite corporate power and authority to enter into this Agreement and to perform its obligations under the terms of this Agreement. All corporate action on the part of the Purchaser, its officers, directors and stockholders necessary for the authorization, execution and delivery of this Agreement have been taken. This Agreement has been duly authorized, executed and delivered by the Purchaser, and, upon due execution and delivery by the Company, this Agreement will be a valid and binding obligation of the Purchaser, enforceable in accordance with its terms, except as enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally or by equitable principles.

- **4.3 No Current Ownership in the Company.** Other than the Shares acquired under this Agreement and the 1,612,904 shares of Common Stock acquired under the Existing Agreement (the "Existing Agreement Shares"), neither the Purchaser, nor to the Purchaser's knowledge, any of its Affiliates own any shares of Common Stock or any rights to acquire Common Stock. To the Purchaser's knowledge, the purchase of the Shares will not result in the Purchaser (individually or together with any other Person with whom the Purchaser has identified, or will have identified, itself as part of a "group" in a public filing made with the SEC involving the Company's securities) acquiring, or obtaining the right to acquire, in excess of 19.999% of the outstanding shares of Common Stock or the voting power of the Company on a post transaction basis that assumes that the Closing shall have occurred. Such Purchaser does not presently intend to, alone or together with others, make a public filing with the SEC to disclose that it has (or that it together with such other Persons have) acquired, or obtained the right to acquire, as a result of such Closing (when added to any other securities of the Company that it or they then own or have the right to acquire), in excess of 19.999% of the outstanding shares of Common Stock or the voting power of the Company on a post transaction basis that assumes that the Closing shall have occurred.
- **4.4 Purchase Entirely for Own Account.** This Agreement is made with the Purchaser in reliance upon the Purchaser's representation to the Company, which the Purchaser hereby confirms by executing this Agreement, that the Shares purchased by the Purchaser will be acquired for investment for the Purchaser's own account, not as a nominee or agent, and not with a view to the resale or distribution of any part thereof, and that the Purchaser has no present intention of selling, granting any participation in, or otherwise distributing the same. Purchaser does not have any contract, undertaking, agreement or arrangement with any Person to sell, transfer or grant participation to such Person or to any third party, with respect to the Shares, if issued.
- **4.5 Disclosure of Information.** The Purchaser has received all the information that it has requested and that it considers necessary or appropriate for deciding whether to enter into this Agreement and to acquire the Shares. The Purchaser further represents that it has had an opportunity to ask questions and receive answers from the Company regarding the terms and conditions of the offering of the Shares; provided, however, that neither such inquiries nor any other investigation conducted by or on behalf of the Purchaser or its representatives or counsel shall modify, amend or affect Purchaser's right to rely on the truth, accuracy and completeness of the Company's representations and warranties contained in this Agreement.

- **4.6 Investment Experience.** The Purchaser acknowledges that it is able to fend for itself, can bear the economic risk of its investment and has such knowledge and experience in financial or business matters that it is capable of evaluating the merits and risks of the investment in the Shares. The Purchaser has not been organized solely for the purpose of acquiring the Shares.
- **4.7 Accredited Investor.** The Purchaser is an "accredited investor" as such term is defined in Rule 501 of the General Rules and Regulations promulgated by the SEC pursuant to the Securities Act.

# **4.8 Restricted Securities.** The Purchaser understands that:

- (a) the Shares will not be registered under the Securities Act by reason of a specific exemption therefrom, and that the Purchaser must, therefore, bear the economic risk of such investment, unless and until a subsequent disposition thereof is registered under the Securities Act or is exempt from such registration, such as under Rule 144 of the Securities Act ("Rule 144");
  - **(b)** each book entry entitlement representing the Shares will be noted with the following legends:
- (i) THE SECURITIES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933 (THE "ACT") AND MAY NOT BE OFFERED, SOLD OR OTHERWISE TRANSFERRED, ASSIGNED, PLEDGED OR HYPOTHECATED UNLESS AND UNTIL REGISTERED UNDER THE ACT OR UNLESS THE COMPANY HAS RECEIVED AN OPINION OF COUNSEL SATISFACTORY TO THE COMPANY AND ITS COUNSEL THAT SUCH REGISTRATION IS NOT REQUIRED; and
  - (ii) Any legend required to be placed thereon under applicable state securities laws.

(c)	The Company will instruct its transfer agent not to register the transfer of the Shares (or any
portion thereof) unless the cor	ditions specified in the foregoing legends are satisfied, until such time as a transfer is made,
pursuant to the terms of this A	greement, and in compliance with Rule 144 or pursuant to a registration statement or, if the opinion
of counsel referred to above is	to the further effect that such legend is not required in order to establish compliance with any
provisions of the Securities A	et or this Agreement.

- **4.9 No Short Sales.** The Purchaser has not engaged, and will not engage, in any short sales of the Company's Common Stock within the three-month period prior to the Closing Date.
- **4.10 No Legal, Tax or Investment Advice.** The Purchaser understands that nothing in the SEC Filings, this Agreement or any other materials presented to the Purchaser in connection with the purchase and sale of the Shares constitutes legal, tax or investment advice and that independent legal counsel has reviewed these documents and materials on the Purchaser's behalf. The Purchaser has consulted such legal, tax and investment advisors as it, in its sole discretion, has deemed necessary or appropriate in connection with its purchase of the Shares.

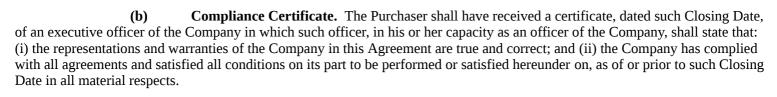
# 5. CONDITIONS TO THE COMPANY'S OBLIGATIONS AT CLOSING

- **5.1 Closing**. The Company's obligation to sell, issue and deliver the Shares to the Purchaser at the Closing shall be subject to the following conditions to the extent not waived by the Company:
- **(a) Receipt of Payment**. The Company shall have received payment in full, by wire transfer of immediately available funds, for the Shares at the Share Price.
- **(b) Representations and Warranties; Obligations.** The representations and warranties made by the Purchaser in Section 4 hereof shall be true and correct on the Closing Date. The Purchaser shall have performed and complied with all obligations and conditions required to be performed and complied with by the Purchaser under this Agreement on, as of or prior to the Closing Date.

- **(c) Follow-On Offering.** The closing of the Follow-On Offering shall have been consummated resulting in receipt by the Company of aggregate gross proceeds of at least \$100,000,000.
- **(d) Antitrust Filings.** The waiting period applicable to the Antitrust Filings shall have expired or terminated.
  - **(e) Collaboration Agreement**. The Collaboration Agreement shall remain in full force and effect.
- **(f) Laws or Orders.** (i) No Governmental Authority of competent jurisdiction shall have enacted, issued, promulgated, enforced or entered any Law or order (whether temporary, preliminary or permanent) that is in effect and restrains, enjoins, makes illegal or otherwise prohibits the consummation of the transactions contemplated hereunder, and (ii) no Governmental Authority of competent jurisdiction shall have instituted any proceeding (which remains pending at what would otherwise be the Closing) seeking to temporarily or permanently enjoin, restrain or otherwise prohibit consummation of the transactions contemplated hereunder.
- **(g) No Investigation**. No investigation is pending before any Governmental Authority, the outcome of which may result in litigation aimed at prohibiting the consummation of the transactions contemplated hereunder.

# 6. CONDITIONS TO THE PURCHASER'S OBLIGATIONS AT CLOSING

- **6.1 Closing.** The Purchaser's obligation to accept delivery of and pay for the Shares at the Closing shall be subject to the following conditions to the extent not waived by the Purchaser:
- **(a) Representations and Warranties; Obligations.** The representations and warranties made by the Company in Section 3 hereof shall be true and correct on the Closing Date. The Company shall have performed and complied with all obligations and conditions to be performed and complied with by the Company under this Agreement on, as of or prior to the Closing Date.



- **(c) Secretary's Certificate.** The Purchaser shall have received a certificate, dated such Closing Date, of the secretary of the Company in which such secretary, in his or her capacity as secretary of the Company, shall certify and attach the resolutions of the Board of Directors of the Company approving the Agreement and the transactions contemplated hereunder, and shall certify that such resolutions have not been amended or modified and remain in full force and effect.
- **(d) Good Standing Certificate.** The Purchaser shall have received a certificate from the Secretary of State of the State of Delaware dated within three (3) Business Days of such Closing Date evidencing the good standing and legal corporate existence of the Company.
- **(e) Opinion of Counsel to the Company.** The Purchaser shall have received an opinion, dated such Closing Date, of Goodwin Procter LLP, counsel for the Company, in the form attached hereto as Exhibit A.
  - **(f) Listing.** The Company's Common Stock shall be listed and trade on the Nasdaq Global Market.
- **(g) Follow-On Offering.** The closing of the Follow-On Offering shall have been consummated resulting in receipt by the Company of aggregate gross proceeds of at least \$100,000,000.
- **(h) Antitrust Filings.** The waiting period applicable to the Antitrust Filings shall have expired or terminated.
  - **(i) Collaboration Agreement**. The Collaboration Agreement shall remain in full force and effect.

- **(j)** Laws or Orders. (i) No Governmental Authority of competent jurisdiction shall have enacted, issued, promulgated, enforced or entered any Law or order (whether temporary, preliminary or permanent) that is in effect and restrains, enjoins, makes illegal or otherwise prohibits the consummation of the transactions contemplated hereunder, and (ii) no Governmental Authority of competent jurisdiction shall have instituted any proceeding (which remains pending at what would otherwise be the Closing) seeking to temporarily or permanently enjoin, restrain or otherwise prohibit consummation of the transactions contemplated hereunder.
- **(k) No Investigation**. No investigation is pending before any Governmental Authority, the outcome of which may result in litigation aimed at prohibiting the consummation of the transactions contemplated hereunder.

# 7. Additional Covenants.

- **7.1 Restricted Transactions**. The last sentence of Section 7.2 of the Existing Agreement shall apply to the Shares.
- **7.2 Shareholder Rights Plan.** No claim will be made or enforced by the Company or, with the consent of the Company, any other Person, that the Purchaser is an "Acquiring Person" under any control share acquisition, business combination, poison pill (including any distribution under a rights agreement) or similar anti-takeover plan or arrangement in effect or hereafter adopted by the Company, or that the Purchaser could be deemed to trigger the provisions of any such plan or arrangement, in either case solely by virtue of Purchaser purchasing the Shares under this Agreement.
- **7.3 Nasdaq Listing.** In the time and manner required by Nasdaq, the Company shall prepare and file with Nasdaq an additional shares listing application covering all of the Shares and shall use its reasonable best efforts to take all steps necessary to cause all of the Shares to be approved for listing on Nasdaq. The Company shall maintain compliance with all listing and maintenance requirements of Nasdaq on the date hereof, except for any noncompliance or deficiencies that may occur under Rules 5605(b)(1), 5605(c)(2), 5605(d)(2), 5450(a)(1), or 5250(c)(1) of the Nasdaq listing rules and in the event of any noncompliance or deficiency pursuant to such rules the Company shall use its reasonable best efforts to regain compliance in

accordance with applicable Nasdaq procedures and cure periods such as to avoid any suspension of trading of the Company's Common Stock on Nasdaq or delisting actions by Nasdaq.

**Legend Removal.** The legends set forth in Section 4.8(b) above shall be removed and the Company shall instruct its transfer agent for the Common Stock (the "Transfer Agent") to register the Shares in book-entry form free and clear of such legends or any other legends by electronic delivery at the applicable balance account at the Depository Trust Company, if (i) such Shares have been resold under an effective registration statement under the Securities Act. (ii) such Shares are sold or transferred in connection with a resale transaction in compliance with Rule 144 (if the transferor is not an Affiliate of the Company), (iii) such Shares are eligible for resale under Rule 144, without the requirement for the Company to be in compliance with the current public information required under Rule 144 as to such Shares and without volume or manner-of-sale restrictions or (iv) if such legend is not required under applicable requirements of the Securities Act (including judicial interpretations and pronouncements issued by the staff of the SEC). The Company further agrees that it shall cause its counsel (x) after the effective date of a registration statement registering the resale of the Shares, to issue to the Transfer Agent, if required by the Transfer Agent, a "blanket" legal opinion or other letter to allow sales without restriction pursuant to the effective registration statement and (y) provide all other opinions of counsel as may reasonably be required by the Transfer Agent in connection with the removal of legends pursuant to this Section 7.4. Following Rule 144 becoming available for the resale of the Shares without the requirement for the Company to be in compliance with the current public information required under Rule 144 as to the Shares and without volume or manner-of-sale restrictions, the Company, upon the request of the Purchaser, shall issue, or shall cause Company counsel or other counsel satisfactory to the Transfer Agent to issue to the Transfer Agent a letter of instruction stating that any and all restrictive legends under the Securities Act may be removed. Any fees (with respect to the Transfer Agent, Company counsel or otherwise) associated with the issuance of such opinion or the removal of such legends shall be borne by the Company. The Company may not make any notation on its records or give instructions to the Transfer Agent that enlarge the restrictions on transfer set forth in Section 4.8(b).

- **7.5 Registration Rights.** The registration rights and other provisions contained in Section 7.7 of the Existing Agreement shall apply to the Shares.
- 7.6 **Antitrust Filings.** The parties shall cooperate in the timely preparation and submission of any necessary Antitrust Filings, and each shall request early termination of any applicable waiting period(s) relating to the Antitrust Filings. Each of the Company and the Purchaser shall promptly supply the other with any information that may be required in order to effectuate or obtain any applicable consents in connection with all required Antitrust Filings. Except where prohibited by applicable laws, and subject to the confidentiality obligations in the Collaboration Agreement and any joint defense agreement entered into between the parties, each of the Company and the Purchaser (and their respective Affiliates), in order to comply with any applicable antitrust or competition laws and regulations or obtain any applicable consents in connection with all required Antitrust Filings, shall (A) consult with the other prior to taking a position with respect to any Antitrust Filings or applicable antitrust or competition laws and regulations, (B) to the extent reasonably required to permit appropriate coordination of efforts, permit the other to review and discuss in advance, and consider in good faith the views of the other in connection with, any analyses, appearances, presentations, memoranda, briefs, white papers, arguments, opinions, and proposals before making or submitting any of the foregoing to any Governmental Authority, (C) coordinate with the other in preparing and exchanging such information, (D) promptly provide the other (and their counsel) with copies of presentations or other advocacy submissions (and a summary of any oral presentations) made by such party to any Governmental Authority, and (E) promptly provide the other (and their counsel) with advance notice of, and an opportunity to attend as an observer (to the extent permitted by the applicable Governmental Authority), any meeting with any Governmental Authority in connection with the consummation of the private placement pursuant to the Company Participation Right. Each of the Company and the Purchaser (and their respective Affiliates) will notify the other promptly upon the receipt of (x) any comments from any Governmental Authority in connection with any Antitrust Filings made pursuant to this Agreement, and (y) any request by any Governmental Authority for amendments or supplements to any Antitrust Filings made pursuant to, or for information provided to comply in all material respects with, any applicable antitrust or competition laws and regulations.

# 8. MISCELLANEOUS.

- **8.1 Termination**. This Agreement may be terminated by the Purchaser, as to such Purchaser's obligations hereunder only, by written notice to the Company, if the Closing has not been consummated on or before September 8, 2020; provided, however, that nothing contained in this Section 8.1 shall relieve any party from liability for fraud or any intentional or willful breach of this Agreement.
- **8.2 Waivers and Amendments.** Any term of this Agreement may be amended and the observance of any term of this Agreement may be waived (either generally or in a particular instance and either retroactively or prospectively), only with the written consent of both the Company and the Purchaser.
- **8.3 Severability.** If one or more provisions of this Agreement are held to be unenforceable under applicable law, such provision(s) shall be excluded from this Agreement and the balance of the Agreement shall be interpreted as if such provision(s) were so excluded and shall be enforceable in accordance with its terms.
- **8.4 Governing Law; Submission to Jurisdiction.** This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware, without regard to conflicts of law principles that would require the application of the Law of any other jurisdiction. Any action brought, arising out of, or relating to this Agreement shall be brought in the Court of Chancery of the State of Delaware. Each party hereby irrevocably submits to the exclusive jurisdiction of said Court in respect of any claim relating to the validity, interpretation and enforcement of this Agreement, and hereby waives, and agrees not to assert, as a defense in any action, suit or proceeding in which any such claim is made that it is not subject thereto or that such action, suit or proceeding may not be brought or is not maintainable in such courts, or that the venue thereof may not be appropriate or that this agreement may not be enforced in or by such courts. The parties hereby consent to and grant the Court of Chancery of the State of Delaware jurisdiction over such parties and over the subject matter of any such claim and agree that mailing of process or other papers in connection with any such action, suit or proceeding in the manner provided in Section 8.10 or in such other manner as may be permitted by law, shall be valid and sufficient thereof.

- **8.5 Counterparts.** This Agreement may be executed in two or more counterparts, each of which shall be deemed an original document, and all of which, together with this writing, shall be deemed one instrument. Facsimile and electronic (PDF) signatures shall be as effective as original signatures.
- **8.6 Successors and Assigns.** Except as expressly provided hereunder, neither this Agreement nor any rights or obligations hereunder may be assigned or otherwise transferred by either party without the prior written consent of the other party; *provided*, *however*, that either party may assign this Agreement and its rights and obligations hereunder without the other party's consent in connection with the transfer or sale of all or substantially all of the business of such party to which the Collaboration Agreement relates to a third party, whether by merger, sale of stock, sale of assets or otherwise. Notwithstanding the foregoing, the Purchaser may assign any or all of its rights under this Agreement to an Affiliate, provided that the assigning party shall remain liable and responsible to the non-assigning party hereto for the performance and observance of all such duties and obligations by such Affiliate.

The rights and obligations of the parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the parties. Any assignment not in accordance with this Agreement shall be void.

- **8.7 Entire Agreement.** This Agreement and the other documents referred to herein constitute the entire agreement among the parties and no party shall be liable or bound to any other party in any manner by any warranties, representations, or covenants except as specifically set forth herein.
- **8.8 Payment of Fees and Expenses.** Each of the Company and the Purchaser shall bear its own expenses and legal fees incurred on its behalf with respect to this Agreement and the transactions contemplated hereby; provided, that upon the Closing, the Company shall pay the reasonable fees and expenses of counsel for the Purchaser in connection with the preparation and negotiation of this Agreement and the consummation of the transactions contemplated hereby, in an amount not to exceed \$25,000 in the aggregate. If any action at law or in equity is necessary to enforce or interpret the terms of this Agreement, the prevailing party shall be entitled to reasonable attorney's fees, costs and necessary disbursements in addition to any other relief to which such party may be entitled.

- 8.9 **Broker's Fee.** Each of the Company and the Purchaser hereby represents that there are no brokers or finders entitled to compensation in connection with the sale of the Shares, and each party shall indemnify the other party for any such fees for which such party is responsible.
- 8.10 Notices. Any notice required or permitted to be given by this Agreement shall be in writing and in English and shall be (a) delivered by hand or overnight courier with tracking capabilities; (b) mailed postage prepaid by first class, registered or certified mail addressed as set forth below or (c) sent by electronic mail or facsimile unless changed by notice so given:

If to the Purchaser:

[\*\*\*]

with a copy (which shall not constitute notice) to:

[\*\*\*]

with a further copy (which shall not constitute notice) to:

[\*\*\*]

If to the Company:

Fate Therapeutics, Inc. 3535 General Atomics Court Suite 200 San Diego, California, 92121 Attention: Chief Executive Officer E-Mail: [\*\*\*]

and

Fate Therapeutics, Inc. 3535 General Atomics Court Suite 200 San Diego, California, 92121 Attention: Office of the General Counsel

E-Mail: [\*\*\*]

Any such notice shall be deemed given (i) on the date received if delivered in accordance with Section 8.10(a), (ii) five (5) Business Days after mailing if mailed in accordance with Section 8.10(b) or (iii) if delivered in accordance with Section 8.10(c), on the date received if sent during normal business hours of the recipient, and if not sent during normal business hours, on the recipient's 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 party's notices in accordance with this Section 8.10. It is understood and agreed that this Section 8.10 does not intend to govern day-today business communications necessary between the parties in performing their duties under the terms of the Collaboration Agreement.

Securities Laws Disclosure; Publicity. The Company shall file a Current Report on Form 8-K, including 8.11 this Agreement as an exhibit thereto or to the Company's Quarterly Report on Form 10-Q or Annual Report on Form 10-K covering the quarterly period in which this Agreement becomes effective, with the SEC within the time required by the Exchange Act, each of which must be agreed to by both parties or one of their respective Affiliates. The Company and the Purchaser, or any of their respective Affiliates, shall consult with each other in issuing any press releases with respect to the transactions contemplated hereby and neither the Company nor the Purchaser shall issue any such press release nor otherwise make any such public statement without the prior consent of the Company, with respect to any press release of the Purchaser, or without the prior consent of the Purchaser, with respect to any press release of the Company, which consent shall not unreasonably be withheld or delayed, except if such disclosure is required by law, in which case the Company shall allow the Purchaser or an Affiliate of the Purchaser, to the extent reasonably practicable in the circumstances, reasonable time to comment on such release or announcement in advance of such issuance. The Company shall not publicly disclose the name of the Purchaser or an Affiliate of the Purchaser, or include the name of the Purchaser or an Affiliate of the Purchaser in any press release or filing with the SEC or any regulatory agency or Nasdaq, without the prior written consent of the Purchaser or an Affiliate of Purchaser, except (a) as required by federal securities law in connection with (i) any registration statement contemplated by the registration rights agreement herein or (ii) the filing of a Current Report on Form 8-K, or Company's Quarterly Report on Form 10-Q or Annual Report on Form 10-K, or this Agreement (including signature pages thereto) with the SEC, (b) to the extent such disclosure is required by law, request of the staff of the SEC or

Nasdaq regulations, in which case the party that is required to make such disclosure shall provide the other party (or, in the event that Purchaser is such other party, an Affiliate of Purchaser) with prior written notice of such disclosure permitted under this subclause (b), or (c) the information is already in the public domain through no breach of this Section 8.11.

- **8.12 Headings.** The headings of the various sections of this Agreement have been inserted for convenience of reference only and shall not be deemed to be part of this Agreement.
- **8.13 Disclaimer**. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY TO THE OTHER PARTY OF ANY NATURE, EXPRESS OR IMPLIED.
- **8.14 Limitation of Liability**. NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT.
- **8.15 Waiver.** In accordance with Section 7.1(a) of the Existing Agreement, the Company delivered written notice of the Company's decision to exercise the Company Participation Right on June 5, 2020. Purchaser hereby waives the requirement set forth in Section 7.1(a) of the Existing Agreement that such notice be delivered at least fifteen (15) days prior to the date of the Follow-On Offering closing.

[SIGNATURE PAGE TO FOLLOW]

**IN WITNESS WHEREOF**, the parties hereto have caused this Stock Purchase Agreement to be executed by their duly authorized representatives as of the day and year first above written.

FATE THERAPEUTICS, INC.

By: /s/ J. Scott Wolchko

Name: J. Scott Wolchko

Title: President and Chief Executive Officer

JOHNSON & JOHNSON INNOVATION – JJDC, INC.

By: /s/ Asish K. Xavier

Name: Asish K. Xavier

Title: VP, Venture Investments

[SIGNATURE PAGE TO STOCK PURCHASE AGREEMENT]

# CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO RULE 13a-14(a) AND 15d-14(a) OF THE SECURITIES EXCHANGE ACT, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

#### I, J. Scott Wolchko, certify that:

- 1. I have reviewed this quarterly report on Form 10-Q of Fate 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 and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
- a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
- b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
- c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
- d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
- a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
- b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 5, 2020 /s/ J. Scott Wolchko

J. Scott Wolchko President and Chief Executive Officer (Principal Executive and Financial Officer)

# 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 of Fate Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, J. Scott Wolchko, Principal Executive Officer and Principal Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

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

Date: August 5, 2020

/s/ J. Scott Wolchko

J. Scott Wolchko President and Chief Executive Officer (Principal Executive and Financial Officer)

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350 and is not being filed as part of the Report or as a separate disclosure document.