

SECURITIES AND EXCHANGE COMMISSION

FORM 10-Q

Quarterly report pursuant to sections 13 or 15(d)

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FILER

Celcuity Inc.

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SIC: **8071** Medical laboratories

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2021

OR

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

For the transition period from _____ to _____

Commission File No. 001-38207

CELCUITY INC.

(Exact name of registrant as specified in its charter)

Delaware

(State of incorporation)

No. 82-2863566

(IRS Employer Identification No.)

16305 36th Avenue North; Suite 100

Minneapolis, Minnesota 55446(Address of principal executive offices, including zip code)

Registrant's telephone number, including area code: (763) 392-0767

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.001 par value per share	CELC	The Nasdaq Stock Market LLC

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

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

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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

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

On August 2, 2021 there were 14,904,898 shares of the registrant's common stock, \$0.001 par value per share, outstanding.

Celcuity Inc.
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As used in this report, the terms "we," "us," "our," "Celcuity," and the "Company" mean Celcuity Inc., unless the context indicates another meaning.

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Celcuity Inc.
Condensed Balance Sheets

	June 30, 2021	December 31, 2020
	(unaudited)	
Assets		
Current Assets:		
Cash and cash equivalents	\$ 41,638,623	\$ 11,637,911
Deposits	22,009	22,009
Deferred transaction costs	121,307	-
Payroll tax receivable	190,000	190,000
Prepaid assets	279,544	317,040
Total current assets	42,251,483	12,166,960
Property and equipment, net	415,080	558,876
Operating lease right-of-use assets	142,766	230,911
Total Assets	\$ 42,809,329	\$ 12,956,747
Liabilities and Stockholders' Equity:		
Current Liabilities:		
Accounts payable	\$ 647,172	\$ 217,377
Finance lease liabilities	5,830	5,810
Operating lease liabilities	153,684	187,518
Accrued expenses	729,672	774,612
Total current liabilities	1,536,358	1,185,317
Finance lease liabilities	5,379	8,299
Operating lease liabilities	-	60,861
Note payable, non-current	14,233,068	-
Total Liabilities	15,774,805	1,254,477
Stockholders' Equity:		
Preferred stock, \$0.001 par value: 2,500,000 shares authorized; 0 shares issued and outstanding as of June 30, 2021 and December 31, 2020	-	-
Common stock, \$0.001 par value: 25,000,000 shares authorized; 12,654,898 and 10,299,822 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively	12,655	10,300
Additional paid-in capital	70,167,970	38,013,551
Accumulated deficit	(43,146,101)	(26,321,581)
Total Stockholders' Equity	27,034,524	11,702,270
Total Liabilities and Stockholders' Equity	\$ 42,809,329	\$ 12,956,747

See accompanying notes to the financial statements

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Celcuity Inc.
Condensed Statements of Operations
(unaudited)

	Three Months Ended June		Six Months Ended June 30,	
	2021	30, 2020	2021	2020
Operating expenses:				
Research and development	\$ 13,070,108	\$ 1,766,227	\$ 15,306,451	\$ 3,613,641
General and administrative	573,360	447,714	1,128,787	911,113
Total operating expenses	<u>13,643,468</u>	<u>2,213,941</u>	<u>16,435,238</u>	<u>4,524,754</u>
Loss from operations	<u>(13,643,468)</u>	<u>(2,213,941)</u>	<u>(16,435,238)</u>	<u>(4,524,754)</u>
Other income (expense)				
Interest expense	(391,187)	(31)	(391,210)	(64)
Interest income	1,803	11,983	2,191	75,834
Loss on sale of fixed assets	-	-	(263)	-
Other income (expense), net	<u>(389,384)</u>	<u>11,952</u>	<u>(389,282)</u>	<u>75,770</u>
Net loss before income taxes	<u>(14,032,852)</u>	<u>(2,201,989)</u>	<u>(16,824,520)</u>	<u>(4,448,984)</u>
Income tax benefits	-	-	-	-
Net loss	<u>\$ (14,032,852)</u>	<u>\$ (2,201,989)</u>	<u>\$ (16,824,520)</u>	<u>\$ (4,448,984)</u>
Net loss per share, basic and diluted	\$ (1.11)	\$ (0.21)	\$ (1.42)	\$ (0.43)
Weighted average common shares outstanding, basic and diluted	12,610,917	10,260,234	11,845,758	10,257,111

See accompanying notes to the financial statements

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Condensed Statements of Changes in Stockholders' Equity
Three Months and Six Months Ended June 30, 2021

	<u>Common Stock</u>		<u>Additional Paid-In Capital</u>	<u>Accumulated Deficit</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>			
Balance at December 31, 2020	10,299,822	\$ 10,300	\$ 38,013,551	\$ (26,321,581)	\$ 11,702,270
Stock-based compensation	-	-	449,098	-	449,098
Exercise of common stock warrants	1,185	1	11,256	-	11,257
Exercise of common stock options, net of shares withheld for exercise price	12,707	13	(13)	-	-
Issuance of common stock upon closing of follow-on offering, net of underwriting discounts and offering costs	1,971,100	1,971	25,766,522	-	25,768,493
Issuance of common stock in an at-the-market ("ATM") offering	3,082	3	38,959	-	38,962
Issuance costs associated with ATM offering	-	-	(3,868)	-	(3,868)
Net loss	-	-	-	(2,791,668)	(2,791,668)
Balance at March 31, 2021 (unaudited)	<u>12,287,896</u>	<u>\$ 12,288</u>	<u>\$ 64,275,505</u>	<u>\$ (29,113,249)</u>	<u>\$ 35,174,544</u>
Stock-based compensation	2,964	3	540,314	-	540,317
Employee stock purchases	5,496	6	25,811	-	25,817
Exercise of common stock options, net of shares withheld for exercise price	9,136	9	36,850	-	36,859
Warrant issued - note payable	-	-	289,839	-	289,839
Issuance of common stock, licensing agreement	349,406	349	4,999,651	-	5,000,000
Net loss	-	-	-	(14,032,852)	(14,032,852)
Balance at June 30, 2021 (unaudited)	<u>12,654,898</u>	<u>\$ 12,655</u>	<u>\$ 70,167,970</u>	<u>\$ (43,146,101)</u>	<u>\$ 27,034,524</u>

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Celcuity Inc.
Condensed Statements of Changes in Stockholders' Equity
Three Months and Six Months Ended June 30, 2020

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total
	Shares	Amount			
Balance at December 31, 2019	10,253,988	\$ 10,254	\$ 36,134,723	\$ (16,847,406)	\$ 19,297,571
Stock-based compensation	-	-	464,649	-	464,649
Net loss	-	-	-	(2,246,995)	(2,246,995)
Balance at March 31, 2020 (unaudited)	10,253,988	\$ 10,254	\$ 36,599,372	\$ (19,094,401)	\$ 17,515,225
Stock-based compensation	15,686	16	423,177	-	423,193
Employee stock purchases	4,678	4	23,893	-	23,897
Issuance of common stock in an at-the-market ("ATM") offering	14,901	15	154,127	-	154,142
Issuance costs associated with ATM offering	-	-	(52,110)	-	(52,110)
Net loss	-	-	-	(2,201,989)	(2,201,989)
Balance at June 30, 2020 (unaudited)	<u>10,289,253</u>	<u>\$ 10,289</u>	<u>\$ 37,148,459</u>	<u>\$ (21,296,390)</u>	<u>\$ 15,862,358</u>

See accompanying notes to the financial statements

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Celcuity Inc.
Condensed Statements of Cash Flows
(unaudited)

	Six Months Ended June 30,	
	2021	2020
Cash flows from operating activities:		
Net loss	\$ (16,824,520)	\$ (4,448,984)
Adjustments to reconcile net loss to net cash used for operations:		
Depreciation	176,597	191,134
Stock-based compensation	989,415	887,842
Issuance of common stock, licensing agreement	5,000,000	-
Amortization of debt issuance costs and discount	81,571	-
PIK interest	93,397	-
Loss on sale of fixed assets	263	-
Changes in operating assets and liabilities:		
Prepaid assets and deposits	37,496	41,952
Accounts payable	438,018	(59,025)
Accrued expenses	(124,940)	26,189
Non-cash operating lease, net	(6,550)	(28,754)
Net cash used for operating activities	<u>(10,139,253)</u>	<u>(3,389,646)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(57,897)	(66,589)
Proceeds from sale of property and equipment	500	-

Net cash used for investing activities	(57,397)	(66,589)
Cash flows from financing activities:		
Proceeds from exercise of common stock warrants	11,257	-
Proceeds from exercise of employee stock options	36,859	-
Proceeds from employee stock purchases	25,817	23,897
Proceeds from follow-on offering, net of underwriting discounts and offering costs	25,768,493	-
Proceeds from note payable, net of debt issuance costs and discount of \$652,061	14,347,939	-
Gross proceeds from an ATM offering	38,962	154,142
Payments for secondary registration statement costs	(29,065)	(23,367)
Payments for finance leases	(2,900)	(2,880)
Net cash provided by financing activities	40,197,362	151,792
Net change in cash and cash equivalents	30,000,712	(3,304,443)
Cash and cash equivalents:		
Beginning of period	11,637,911	18,735,002
End of period	41,638,623	\$ 15,430,559
Supplemental disclosures of non-cash investing and financing activities:		
Offering and registration statement costs included in accounts payable and accrued expenses	\$ 96,111	\$ -
Issuance of common stock warrants and final fee recognized as discount to note payable	\$ 964,839	\$ -

See accompanying notes to the financial statements

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CELCUITY INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS (unaudited)
(For the Three and Six Months Ended June 30, 2021 and 2020)

1. Organization

Nature of Business

Celcuity Inc., a Delaware corporation (the “Company”), is a clinical-stage biotechnology company seeking to extend the lives of cancer patients by pursuing an integrated companion diagnostic (CDx) and therapeutic (Rx) strategy. Our CELsignia companion diagnostic platform is uniquely able to analyze live patient tumor cells to identify new groups of cancer patients likely to benefit from targeted therapies. This enables a CELsignia CDx to support advancement of new indications for already approved targeted therapies. Our therapeutic efforts are focused on in-licensing and developing molecularly targeted therapies that address the same cancer driver our companion diagnostics can identify. By pursuing an integrated companion diagnostic and therapeutic strategy, we believe we are uniquely positioned to achieve our goal of helping cancer patients receive the therapeutic best suited to treat their cancer driver. The Company was co-founded in 2012 by Brian F. Sullivan and Dr. Lance G. Laing and is based in Minnesota. The Company has not generated any revenues to date.

Follow-on Offering

On July 1, 2021, the Company completed a follow-on offering whereby it sold 2,250,000 shares of common stock at a public offering price of \$25.00 per share. The aggregate gross proceeds from the sale of shares in the follow-on offering was approximately \$56.3 million before deducting underwriting discounts of approximately \$3.4 million and offering expenses of approximately \$0.1 million.

2. Basis of Presentation, Summary of Significant Accounting Policies and Recent Accounting Pronouncements

Basis of Presentation

The accompanying unaudited financial statements include the accounts of the Company and have been prepared in accordance with Article 10 of Regulation S-X promulgated by the Securities and Exchange Commission (“SEC”). Accordingly, as permitted by Article

10, the unaudited financial statements do not include all of the information required by accounting principles generally accepted in the United States ("U.S. GAAP"). The balance sheet at December 31, 2020 was derived from the audited financial statements at that date and does not include all the disclosures required by U.S. GAAP. In the opinion of management, all adjustments which are of a normal recurring nature and necessary for a fair presentation have been reflected in the financial statements. These unaudited condensed financial statements should be read in conjunction with the audited financial statements as of and for the year ended December 31, 2020 and the related footnotes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2020. Operating results for the three and six months ended June 30, 2021 are not necessarily indicative of the results to be expected during the remainder of the current year or for any future period.

Accounting Estimates

Management uses estimates and assumptions in preparing these unaudited condensed financial statements in accordance with U.S. GAAP. Those estimates and assumptions affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities, and the reported revenues and expenses. Actual results could differ from those estimates and the difference could be material. Significant items subject to such estimates and assumptions include the valuation of stock-based compensation and prepaid or accrued clinical trial costs.

Risks and Uncertainties

The Company is subject to risks common to companies in the development stage including, but not limited to, dependency on the clinical and commercial success of its diagnostic tests, ability to obtain regulatory approval of its diagnostic tests, the clinical and commercial success of its initial drug product, gedatolisib, the need for substantial additional financing to achieve its goals, uncertainty of broad adoption of its approved products, if any, by physicians and consumers, and significant competition.

Clinical Trial Costs

The Company records prepaid assets or accrued expenses for prepaid or estimated clinical trial costs conducted by third-party service providers, which includes the conduct of preclinical studies and clinical trials. These costs can be a significant component of the Company's research and development expenses. The Company accrues for these costs based on factors such as estimates of the work completed and in accordance with service agreements with its third-party service providers. The Company makes significant judgments and estimates in determining the accrued liabilities balance in each reporting period. As actual costs become known, the Company adjusts its prepaid assets or accrued expenses. The Company has not experienced any material differences between accrued costs and actual costs incurred. However, the status and timing of actual services performed, number of patients enrolled, and the rate of patient enrollments may vary from the Company's estimates, resulting in an adjustment to expense in future periods. Changes in these estimates that result in material changes to the Company's prepaid assets or accrued expenses could materially affect the Company's results of operations.

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Application of New or Revised Accounting Standards

Pursuant to the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"), a company constituting an "emerging growth company" is, among other things, entitled to rely upon certain reduced reporting requirements. The Company is an emerging growth company but has irrevocably elected not to take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards. As a result, the Company will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for public companies that are not emerging growth companies.

Recently Adopted Accounting Pronouncements

In August 2020, the FASB issued ASU No. 2020-06, Debt - Debt with Conversion and other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity ("ASU 2020-06"), which simplifies accounting for convertible instruments by removing major separation models required under current U.S. GAAP. ASU 2020-06 removes certain settlement conditions that are required for equity contracts to qualify for derivative scope exceptions and also simplifies the diluted earnings per share calculation in certain areas. The standard is effective for public business entities, excluding entities eligible to be smaller reporting companies as defined by the SEC, for fiscal years and interim periods within those fiscal years beginning after December 15, 2021. For all other entities, the standard will be effective for

fiscal years beginning after December 15, 2023. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, and adoption must be as of the beginning of the Company’s annual fiscal year. The Company’s early adoption of this accounting standard on April 8, 2021, in conjunction with the closing of a loan agreement, did not have an impact on the Company’s financial statements and related disclosures.

3. Net Loss Per Common Share

Basic and diluted net loss per common share is determined by dividing net loss attributable to common stockholders by the weighted-average common shares outstanding during the period. For all periods presented, the common shares underlying the options and warrants have been excluded from the calculation because their effect would be anti-dilutive. Therefore, the weighted-average shares outstanding used to calculate both basic and diluted loss per common share are the same.

For the three and six months ended June 30, 2021 and 2020, potentially dilutive securities excluded from the computations of diluted weighted-average shares outstanding were options to purchase 1,023,513 and 723,194 shares of common stock, respectively, warrants to purchase 378,442 and 353,585 shares of common stock, respectively, and 2,964 and 15,686 shares of restricted common stock, respectively.

4. Commitments

Operating and Finance Leases

The Company leases its corporate space in Minneapolis, Minnesota. In September 2017, the Company entered into a non-cancelable operating lease agreement for building space. The new lease commenced, and the Company moved to the facility in May 2018, in conjunction with the termination of its then existing lease. Rent expense is recorded on a straight-line basis over the lease term. In July 2020 the Company signed an amendment to extend this lease through April 30, 2022. The lease amendment provides for monthly rent, real estate taxes and operating expenses. As a result of the lease amendment, the Company recorded an incremental \$197,211 in the operating right-of-use (“ROU”) asset and lease liability.

The lease agreement, as amended, includes the option to extend the term for one additional year. The option to extend is at the Company’s discretion and because the Company has not determined if the option to extend will be exercised, the extended lease term is not included in the ROU assets and lease liabilities. The Company regularly evaluates the renewal options and when it is reasonably certain of exercise, the Company will include the renewal period in its lease term.

In May 2018, the Company entered into a non-cancelable finance lease agreement for office equipment with a five-year term. The underlying assets are included in furniture and equipment. The lease contains a bargain purchase option at the end of the lease.

When an implicit rate is not provided, the Company uses its incremental borrowing rate based on the information available at the lease commencement date in determining the present value of the lease payments.

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Supplemental balance sheet information consisted of the following at June 30, 2021:

Operating Lease	
Right-of-use assets	\$ 142,766
Operating lease liability	
Less: short term portion	(153,684)
Long term portion	<u>\$ -</u>
Finance Lease	
Furniture and equipment	\$ 28,932
Less: Accumulated depreciation	(17,841)
Net book value of property and equipment under finance lease	<u>\$ 11,091</u>

Finance lease liability	\$ 11,209
Less: short term portion	(5,830)
Long term portion	<u>\$ 5,379</u>

Maturity analysis under lease agreements consisted of the following as of June 30, 2021:

	Operating Leases	Finance Leases
2021	\$ 97,411	\$ 3,627
2022	64,940	7,255
2023	-	3,023
Total minimum lease payments	<u>162,351</u>	<u>13,905</u>
Less: Present value discount	(8,667)	(78)
Less amount representing services	-	(2,618)
Present value of net minimum lease payments	<u>\$ 153,684</u>	<u>\$ 11,209</u>

	Remaining Lease Term	Discount Rate
Operating lease	0.8 years	4.0%
Finance lease	1.9 years	1.0%

Lease costs for the period ended June 30, 2021:

	Three- month Period	Six-month Period
Operating lease cost	\$ 43,727	\$ 89,157
Finance lease cost:		
Amortization	1,447	2,893
Interest	21	45
Variable lease cost	19,869	39,738
	<u>\$ 65,064</u>	<u>\$ 131,833</u>

Supplemental cash flow information related to leases for the period ended June 30, 2021:

	Three- month Period	Six-month Period
Cash paid for amounts included in operating and finance leases:		
Operating cash outflow from operating leases	\$ 66,872	\$ 135,446
Operating cash outflow from finance leases	21	45
Financing cash outflow from finance leases	1,451	2,900
	<u>\$ 68,344</u>	<u>\$ 138,391</u>

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Clinical Research Studies

The Company enters into contracts in the normal course of business for clinical trials, preclinical studies, manufacturing and other services and products for operating purposes. The Company currently has five Phase II clinical trial agreements in place to evaluate targeted therapies selected with one of our CELsignia tests. The Company also has a license agreement in place with Pfizer to research, develop, manufacture and commercialize gedatolisib. Timing of milestone payments are uncertain and the contracts generally provide for termination following a certain period after notice, therefore the Company believes that non-cancelable obligations under the agreements are not material.

5. Stockholders' Equity

On February 26, 2021, the Company completed a follow-on offering whereby it sold 1,971,100 shares of common stock (including 257,100 shares of common stock in connection with the full exercise of the underwriters' option to purchase additional shares) at a public offering price of \$14.00 per share. The aggregate gross proceeds from the sale of shares in the follow-on offering, including the sale of shares pursuant to the full exercise of the underwriters' option to purchase additional shares, was approximately \$27.6 million before deducting underwriting discounts of approximately \$1.6 million and offering expenses of approximately \$0.2 million.

On June 5, 2020, the Company entered into an At Market Issuance Sales Agreement (the "ATM Agreement") with B. Riley FBR, Inc. (the "Agent"). Pursuant to the ATM Agreement, the Company was able to offer and sell from time to time, at its option, shares of common stock having an aggregate offering price of up to \$10,000,000, par value \$0.001 per share (the "Placement Shares"), through the Agent.

The Placement Shares were registered under the Securities Act of 1933, as amended, pursuant to the Registration Statement on Form S-3 (File No. 333-227466), which was originally filed with the SEC on September 21, 2018 and declared effective by the SEC on October 4, 2018, the base prospectus contained within the Registration Statement, and a prospectus supplement that was filed on June 5, 2020. Sales of the Company's common stock, if any, under this prospectus supplement were able to be made by any method deemed to be an "at the market offering" as defined in Rule 415 promulgated under the Securities Act of 1933, as amended.

During the six months ended June 30, 2021, the Company sold 3,082 shares of common stock pursuant to the ATM Agreement, at an average selling price of \$12.64 per share.

On February 23, 2021, in conjunction with the Company's follow-on offering, the ATM Agreement was terminated.

6. Stock-Based Compensation

The following table summarizes the activity for all stock options outstanding for the six months ended June 30:

	2021		2020	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Options outstanding at beginning of year	849,949	\$ 9.33	585,215	\$ 14.37
Granted	218,050	24.70	151,231	7.14
Exercised	(39,620)	7.32	-	-
Forfeited	(4,866)	7.67	(13,252)	11.54
Balance at June 30	1,023,513	\$ 12.69	723,194	\$ 9.71
Options exercisable at June 30:	504,189	\$ 9.64	305,778	\$ 9.68
Weighted Average Grant Date Fair Value for options granted during the period:		\$ 16.39		\$ 4.55

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The following table summarizes additional information about stock options outstanding and exercisable at June 30, 2021:

Options Outstanding				Options Exercisable		
Options Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Aggregate Intrinsic Value	Options Exercisable	Weighted Average Exercise Price	Aggregate Intrinsic Value
1,023,513	7.99	\$ 12.69	\$ 12,101,685	504,189	\$ 9.64	\$ 7,271,109

The Company recognized stock-based compensation expense for stock options of \$520,361 and \$414,272 for the three months ended June 30, 2021 and 2020, respectively and \$938,553 and \$864,937 for the six months ended June 30, 2021 and 2020, respectively. In May 2020, the Company modified the exercise price on 203,750 stock option awards to \$5.10, the closing market price on the Nasdaq Capital Market on May 14, 2020. No director or officer awards were modified. The effect on stock-based compensation was \$12,790 and \$51,000 for the three months ended June 30, 2021 and 2020, respectively and \$26,239 and \$51,000 for the six months ended June 30, 2021 and 2020. The effect on stock-based compensation over the remaining service period will be approximately \$109,000.

The Black-Scholes option-pricing model was used to estimate the fair value of equity-based awards with the following weighted-average assumptions for the six months ended June 30:

	2021	2020
Risk-free interest rate	0.63% - 1.14%	0.35% - 1.66%
Expected volatility	76.6% - 76.9%	73.3% - 74.4%
Expected life (years)	5.0 to 6.08	5.5 to 6.12
Expected dividend yield	0%	0%

The inputs for the Black-Scholes valuation model require management's significant assumptions. Prior to the Company's initial public offering, the price per share of common stock was determined by the Company's board based on recent prices of common stock sold in private offerings. Subsequent to the initial public offering, the price per share of common stock is determined by using the closing market price on the Nasdaq Capital Market on the grant date. The risk-free interest rates are based on the rate for U.S. Treasury securities at the date of grant with maturity dates approximately equal to the expected life at the grant date. The expected life is based on the simplified method in accordance with the SEC Staff Accounting Bulletin Nos. 107 and 110. The expected volatility is estimated based on historical volatility information of peer companies that are publicly available in combination with the Company's calculated volatility since being publicly traded.

All assumptions used to calculate the grant date fair value of non-employee options are generally consistent with the assumptions used for options granted to employees. In the event the Company terminates any of its consulting agreements, the unvested options issued in connection with the agreements would also be cancelled.

Restricted stock awards were granted to two members of the Company's board during the three months ended June 30, 2021 and 2020. The Company had 2,964 and 15,686 shares of restricted stock outstanding as of June 30, 2021 and 2020, respectively, and 15,686 and 0 shares of restricted stock vested during the three months ended June 30, 2021 and 2020. The Company recognized stock-based compensation expense for restricted stock of \$18,112 and \$10,912 for the three months ended June 30, 2021 and 2020, respectively and \$38,567 and \$10,912 for the six months ended June 30, 2021 and 2020.

The Company initially reserved a maximum of 750,000 shares of common stock for issuance under the 2017 Amended and Restated Stock Incentive Plan (the "2017 Plan"). The number of shares reserved for issuance was automatically increased by 102,540 shares on January 1, 2020 and by 102,998 shares on January 1, 2021 and will increase automatically on January 1 of each of 2022 through 2027 by the number of shares equal to 1.0% of the aggregate number of outstanding shares of Company common stock as of the immediately preceding December 31. At the Annual Meeting held on May 12, 2021, the stockholders approved a one-time, 500,000 increase to the number of shares reserved for issuance under the 2017 Plan. However, the Company's board may reduce the amount of the increase in any particular year. The total remaining shares available for grant under the Company's 2017 Plan as of June 30, 2021 was 585,772.

Total unrecognized compensation cost related to stock options and restricted stock is estimated to be recognized as follows:

2021	\$ 1,247,486
2022	2,034,829
2023	1,476,348
2024	979,053
2025	246,916
Total estimated compensation cost to be recognized	<u>\$ 5,984,632</u>

The Company recognized stock-based compensation expense related to its employee stock purchase plan of \$1,844 and (\$1,991) for the three months ended June 30, 2021 and 2020, respectively and \$12,295 and \$11,993 for the six months ended June 30, 2021 and 2020, respectively. The Company initially reserved a total of 100,000 shares for issuance under the employee stock purchase plan. The number of shares reserved for issuance was automatically increased by 51,270 shares on January 1, 2020 and 51,499 shares on January 1, 2021 and will increase automatically on each subsequent January 1 by the number of shares equal to 0.5% of the total outstanding number of shares of Company common stock as of the immediately preceding December 31. However, the Company's board may reduce the amount of the increase in any particular year. The total remaining shares available for issuance under the employee stock purchase plan as of June 30, 2021 was 158,214.

The Company recognized total stock-based compensation expense as follows for the three and six months ended June 30:

	Three Months Ended		Six Months Ended	
	2021	2020	2021	2020
Stock-based compensation expense in operating expenses:				
Research and development	\$ 328,077	\$ 265,446	\$ 583,258	\$ 558,562
General and administrative	212,240	157,747	406,157	329,280
Total	<u>\$ 540,317</u>	<u>\$ 423,193</u>	<u>\$ 989,415</u>	<u>\$ 887,842</u>

7. Debt

On April 8, 2021, the Company entered into a loan and security agreement (the "Loan Agreement") with Innovatus Life Sciences Lending Fund I, LP, a Delaware limited partnership ("Innovatus") in its capacity as Collateral Agent and sole Lender. The Lender agreed to loan up to \$25 million in three tranches consisting of (i) a \$15.0 million non-contingent term A loan that was funded on April 8, 2021, (ii) a \$5 million term B loan to be funded upon request of the Company no later than March 31, 2022, and (iii) a \$5 million term C loan to be funded upon request of the Company no later than March 31, 2023 (collectively the "Term Loans"). Funding of the term B and C loan is subject to the Company's ability to achieve certain milestones. The Innovatus Loan Agreement is secured by a lien covering substantially all assets of the Company.

The loan agreement also contains certain events of default, warranties and covenants of the Company. In connection with each funding of the Term Loans, the Company is required to issue Innovatus a warrant (the "Warrants") to purchase a number of shares of the Company's stock equal to 2.5% of the principal amount of the relevant Term Loan funded divided by the exercise price, which will be based on the lower of (i) \$14.40 per share or (ii) the volume weighted price per share of the Company's stock for the five-trading day period ending on the last trading day immediately preceding the funding date of the Term B or Term C Loan, as applicable. The warrants may be exercised on a cashless basis and are immediately exercisable through the tenth anniversary of the applicable funding date. In connection with the first tranche of the Term Loans, the Company issued a warrant to Innovatus to purchase 26,042 shares of the Company's common stock at an exercise price of \$14.40 per share. The Company evaluated the warrant under ASC470, debt, and recognized an additional debt discount of approximately \$0.3 million based on the relative fair value of the base instruments and warrants. The Company calculated the fair value of the warrant using the Black-Scholes model. The Company is also required to maintain a minimum cash balance in agreement with the term loans' default terms.

The Company is entitled to make interest-only payments for thirty-six months, or up to forty-eight months if certain conditions are met. The Term Loans will mature on the fifth anniversary of the initial funding date and will bear interest at a rate equal to sum of (a) the greater of (i) Prime Rate (as defined in the loan agreement) or (ii) 3.25%, plus (b) 5.70%. The effective interest rate is 11.36%. Additionally, the Company elected to make 2.7% of the interest rate as payable in kind, which shall accrue as principal monthly. The Company is obligated to pay the Lender (i) a non-refundable facility fee in the amount of 1.00% of each term loan that is funded (the "Facility Fee"), and (ii) a final fee equal to 4.50% of the aggregate amount of the term loans funded (the "Final Fee"). In connection with the funding of the first tranche of the Term Loans, a final fee of approximately \$0.7 million was recorded as additional principal and as a debt discount, and a facility fee of approximately \$0.1 million was recorded as additional debt discount. The Company has the option to prepay the loan at any time following the first anniversary of the loan closing, with tiered prepayment fees ranging from 0 – 2% based on when the prepayment would occur.

Innovatus also has the right, at its election, after June 1, 2021 and until the third anniversary of the Loan Agreement, to convert up to 20% of the outstanding principal amount of all Terms Loans made under the Loan Agreement into shares of the Company's common stock at a price per share equal to the volume weighted average closing price of the Company's stock for the 5-trading day period ending on the last trading day immediately preceding the execution of the Loan Agreement (the "Conversion Right").

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In connection with the loan agreement and the funding of the first tranche of the Term Loans, the Company incurred debt issuance costs of approximately \$0.5 million. The debt issuance costs, and the debt discount are amortized to interest expense using the effective interest method over the life of the Term Loans. The carrying value of the debt approximates fair value as of June 30, 2021.

Long-term debt consisted of the following:

	June 30, 2021
Note payable	\$ 15,000,000
Add: PIK interest (added to principal)	93,397
Add: final fee	675,000
Less: unamortized debt issuance costs	(466,482)
Less: unamortized debt discount	(1,068,847)
Total long-term debt	<u>\$ 14,233,068</u>

Future principal payments, including the final fee, are as follows:

	Years Ending December 31,
2024	\$ 5,660,024
2025	7,546,698
2026	2,561,675
Total	<u>\$ 15,768,397</u>

8. License Agreement

On April 8th, the Company entered into a license agreement with Pfizer to research, develop, manufacture and commercialize gedatolisib, a potent, well-tolerated, reversible dual inhibitor that targets PI3K and mTOR, for the treatment, diagnosis and prevention of all diseases. The Company paid Pfizer \$5.0 million in upfront fees and issued to Pfizer \$5.0 million of shares of the Company's common stock pursuant to an Equity Grant Agreement. The upfront payment and the issuance of shares were expensed to research & development in full for the three months ending June 30, 2021.

The Company is also required to make milestone payments to Pfizer upon achievement of certain development and commercial milestone events, up to an aggregate of \$335.0 million. Additionally, the Company will pay Pfizer tiered royalties on sales of gedatolisib at percentages ranging from the low to mid-teens, which may be subject to deductions for expiration of valid claims, amounts due under third-party licenses and generic competition. Unless earlier terminated, the License Agreement will expire upon the expiration of all royalty obligations. The royalty period will expire on a country-by-country basis upon the later of (a) 12 years following the date of first commercial sale of such product in such country, (b) the expiration of all regulatory or data exclusivity in such country for such product or (c) the date upon which the manufacture, use, sale, offer for sale or importation of such product in such country would no longer infringe, but for the license granted in the License Agreement, a valid claim of a licensed patent right.

The Company has the right to terminate the License Agreement for convenience upon 90 days' prior written notice. Pfizer may not terminate the agreement for convenience. Either the Company or Pfizer may terminate the License Agreement if the other party is in material breach and such breach is not cured within the specified cure period. In addition, either the Company or Pfizer may terminate the License Agreement in the event of specified insolvency events involving the other party.

9. Subsequent Events

As noted in footnote 2, on July 1, 2021, the Company completed a follow-on offering whereby it sold 2,250,000 shares of common stock at a public offering price of \$25.00 per share.

On July 19, 2021, the Company signed an amendment to exercise the option to extend the lease for a period of one year. The commencement of the extended period is May 1, 2022 and will terminate on April 30, 2023.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited condensed financial statements and the related notes appearing under Item 1 of Part I of this Quarterly Report on Form 10-Q (this "Quarterly Report"). Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to our plans and strategy for our business and expected financial results, includes forward-looking statements that involve risks and uncertainties. You should review the "Risk Factors" discussed in our Annual Report on Form 10-K for the year ended December 31, 2020, in Exhibit 99.4 to our Current Report on Form 8-K, filed with the SEC on April 8, 2021 and elsewhere in this Quarterly Report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical-stage biotechnology company seeking to extend the lives of cancer patients by pursuing an integrated companion diagnostic (CDx) and therapeutic (Rx) strategy that leverages our CELsignia CDx platform. CELsignia is uniquely able to analyze live patient tumor cells to identify new groups of cancer patients likely to benefit from targeted therapies. This enables a CELsignia CDx to support advancement of new indications for already approved targeted therapies. Our therapeutic strategy aims to utilize CELsignia's unique insights into tumor cell biology to identify, in-license, and develop potential first-in-class or best-in-class targeted therapies that treat the same cancer driver a CELsignia CDx can identify. We believe this integrated CDx and Rx strategy will maximize the impact our CELsignia platform has on the treatment landscape for cancer patients.

The first drug candidate we are developing internally is gedatolisib, a potent, well-tolerated, small molecule dual inhibitor, administered intravenously, that selectively targets all Class 1 isoforms of PI3K and mammalian target of rapamycin (mTOR). In April 2021, we obtained exclusive global development and commercialization rights to gedatolisib under a license agreement with Pfizer, Inc. Our interest in gedatolisib was prompted after we conducted a study of various PI3K targeted therapeutics while developing our CELsignia PI3K Activity Test. Our CELsignia platform allows us to obtain proprietary insights about the relative effectiveness of PI3K targeted therapies. This study found that gedatolisib inhibited higher levels of PI3K-involved signaling activity than the other PI3K targeted therapeutics we evaluated and demonstrated superior drug synergy when combined with other targeted therapies. Gedatolisib's initial clinical development program will focus on the treatment of patients with estrogen receptor positive (ER+), HER2-negative, advanced or metastatic breast cancer. Additional clinical development programs are expected to focus on other tumor types that involve a hormonal signaling pathway, such as endometrial, ovarian, or prostate cancer.

Supporting the development of a potential first-in-class targeted therapy for breast cancer, like gedatolisib, with our CELsignia platform is a natural extension of our strategy to use our CELsignia CDx to enable new indications for other companies' targeted therapies. By combining companion diagnostics designed to enable proprietary new drug indications with targeted therapies that treat signaling dysregulation our CDx identifies, we believe we are uniquely positioned to improve the standard-of-care for many early and late-stage breast cancer patients. Our goal is to play a key role in the multiple treatment approaches required to treat breast cancer patients at various stages of their disease. With each program, we are:

- Leveraging the proprietary insights CELsignia provides into live patient tumor cell function
- Using a CELsignia CDx to identify new patients likely to respond to the paired targeted therapy
- Developing a new targeted therapeutic option for breast cancer patients
- Maximizing the probability of getting regulatory approval to market the targeted therapy indication

CELsignia Development and CDx Programs

Our proprietary CELsignia diagnostic platform is the only commercially ready technology we are aware of that uses a patient's living tumor cells to identify the specific abnormal cellular process driving a patient's cancer and the targeted therapy that best treats it. This enables us to identify patients whose tumors may respond to a targeted therapy, even though they lack a previously associated molecular mutation. By identifying cancer patients whose tumors lack an associated genetic mutation but have abnormal cellular activity a matching targeted therapeutic is designed to inhibit, CELsignia CDx can expand the markets for a number of already approved

targeted therapies. Our current CDx identifies breast and ovarian cancer patients whose tumors have cancer drivers potentially responsive to treatment with human epidermal growth factor receptor 2-negative (HER2), mesenchymal-epithelial transition factor (c-MET), or phosphatidylinositol 3-kinases (PI3K) targeted therapeutics. While U.S. Food and Drug Administration (“FDA”) approval or clearance is not currently required for CELsignia tests offered as a stand-alone laboratory developed test, if we are partnered with a drug company to launch a CELsignia test as a companion diagnostic for a new drug indication, we would be required to obtain premarket approval, or PMA, in conjunction with the pharmaceutical company seeking a new drug approval for the matching therapy.

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Our CELsignia platform provides an important advantage over traditional molecular diagnostics. Current molecular diagnostics analyze fragmented cells to obtain a snapshot of the genetic mutations present in a patient’s tumor. Using cell fragments prevents molecular diagnostics from analyzing the dynamic cellular activities, known as cell signaling, that regulate cell proliferation or survival. Cancer can develop when critical cell signaling, regulating physiologic activity such as cell proliferation, becomes abnormal or dysregulated. Since genetic mutations are often only weakly correlated to the dysregulated cell signaling activity driving a patient’s cancer, a molecular diagnostic is prone to providing an incomplete diagnosis. CELsignia tests overcome this limitation by measuring dynamic cell signaling activity in a cancer patient’s living tumor cells. When a CELsignia test detects abnormal signaling activity, a more accurate diagnosis of the patient’s cancer driver is obtained.

We are supporting the advancement of new potential indications for six different targeted therapies, controlled by other pharmaceutical companies, that would rely on a CELsignia CDx to select patients. Five Phase 2 trials are underway to evaluate the efficacy and safety of these therapies in CELsignia selected patients. These patients are not currently eligible to receive these drugs and are not identifiable with a molecular test.

Our first analytically validated and commercially ready test using our CELsignia platform, the CELsignia HER2 Pathway Activity Test for breast cancer, diagnoses two new sub-types of HER2-negative breast cancer that traditional molecular diagnostics cannot detect. Our internal studies show that approximately 15-20% of HER2-negative breast cancer patients have abnormal HER2 signaling activity similar to levels found in HER2-positive breast cancer cells. As a result, these HER2-negative patients have undiagnosed HER2-driven breast cancer and would be likely to respond to the same anti-HER2 targeted therapies only HER2-positive patients receive today. We have three interventional clinical trials underway to evaluate the efficacy of HER2 targeted therapies in breast cancer patients selected with our CELsignia HER2 Pathway Activity Test.

Our second CELsignia test for breast cancer evaluates independent c-Met signaling activity and its involvement with HER family signaling in HER2-negative breast cancer tumor cells. Our internal studies show that approximately 20%-25% of HER2-negative breast cancer patients have abnormal c-Met signaling activity that is co-activated with abnormal HER family signaling. These studies suggest that this sub-group of HER2-negative breast cancer patients may best respond to treatment with a combination of HER family and c-Met inhibitors. We have two interventional clinical trials underway to evaluate the efficacy of HER2 and c-Met targeted therapies, in previously treated metastatic HER2-negative breast cancer patients selected with our CELsignia Multi-Pathway Activity Test, or CELsignia MP Test.

Our third CELsignia test for breast cancer evaluates PI3K signaling in HER2-negative breast cancer tumor cells. Our internal studies demonstrate how measurement of PI3K-involved signaling may provide a more sensitive and specific method of identifying patients most likely to benefit from PI3K inhibitors than current genetic tests that measure PI3K mutations. We intend to combine these three tests to create the CELsignia Multi-Pathway Activity Test, or CELsignia MP Test. With this next generation CELsignia test, we plan to provide an analysis of EGFR/HER1, HER2, HER3, c-MET, and PI3K-node involved signaling activity for each patient tumor specimen received.

We completed development of our first CELsignia test for ovarian cancer in 2020. This test identifies a new sub-group of ovarian cancer patients with tumors that have abnormal c-Met and HER2 signaling activity. These findings suggest that a significant sub-group of ovarian cancer patients may respond to treatment with a combination of ErbB and c-Met inhibitors. Nearly 14,000 women a year die from ovarian cancer, a disease that has less than a 50% five-year survival rate and a limited range of targeted therapy options. There is thus a significant unmet need for additional therapeutic options for ovarian cancer patients. As a companion diagnostic, our CELsignia test for ovarian cancer will be intended to help pharmaceutical companies obtain new drug indications and expand treatment options for this challenging tumor type. We are currently in discussions with pharmaceutical companies about collaborating on future clinical trials.

In addition to our CELsignia tests for HER2-negative breast cancer and ovarian cancer, we expect to develop CELsignia tests to diagnose eight new potential cancer sub-types we have discovered in lung, ovarian, kidney, and bladder cancers. Approved or

investigational drugs are currently available to treat these new potential cancer sub-types. We expect to launch these additional tests on a staggered basis over the next few years while continuing our research to identify additional new cancer sub-types.

Our overall commercialization strategy is to develop diagnostics that expand the patient population eligible for targeted therapies. In furtherance of this strategy, we will seek collaborations with pharmaceutical companies to field clinical trials to advance the clinical development of their targeted therapies with the eventual goal of obtaining FDA approval of a new drug indication. Collaborations are expected to involve initially Phase I or Phase II interventional clinical trials to evaluate the efficacy of our collaboration partners' targeted therapies on patients selected with one of our CELSignia tests. These trials would not be intended to separately evaluate the CELSignia tests, whether as standalone tests or companion diagnostics. While FDA approval or clearance is not currently required for CELSignia tests offered as a stand-alone laboratory developed test, if we are partnered with a drug company to launch a CELSignia test as a companion diagnostic for a new drug indication, we would be required to obtain premarket approval, or PMA, in conjunction with the pharmaceutical company seeking a new drug approval for the matching therapy.

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We are currently collaborating on five Phase II clinical trials to evaluate the efficacy of our collaboration partners' targeted therapies in patients selected with one of our CELSignia tests. The goal of these trials is to support the development of five potential new drug indications to treat patient groups found responsive by our CELSignia test to their approved targeted therapies. These clinical trials include:

- **FACT-1 Clinical Trial to Evaluate Efficacy of Genentech's HER2 Targeted Therapies** – We are collaborating with NSABP Foundation, Inc. (“NSABP”) and Genentech, Inc. (“Genentech”) to evaluate the efficacy and safety of Genentech's drugs, Herceptin (trastuzumab) and Perjeta (pertuzumab), and chemotherapy in breast cancer patients selected with our CELSignia test. Based on NSABP's updated estimates of patient enrollment rates to reflect the impact of COVID-19, interim results are expected in late 2021 or early 2022 and final results approximately nine months later. The goal is to demonstrate that patients who have an abnormal HER2 signaling pathway, as identified by our CELSignia test, respond to treatment with a matching targeted therapy.
- **FACT-2 Clinical Trial to Evaluate Efficacy of Puma's HER2 Targeted Therapy** – We are collaborating with Puma Biotechnology, Inc. (“Puma”) and West Cancer Center to conduct a Phase II single-arm interventional trial to evaluate the efficacy and safety of Puma's drug, Nerlynx (neratinib), and chemotherapy in breast cancer patients selected with our CELSignia test. Based on West Cancer Center's updated estimates of patient enrollment rates to reflect the impact of COVID-19, interim results are expected in late 2021 or early 2022 and final results approximately nine months later. The goal of the trial is to demonstrate that triple-negative breast cancer patients who have a hyperactive HER2 signaling tumor, as identified by the CELSignia test, respond to treatment with Nerlynx, a matching HER2 therapy.
- **FACT-3 Clinical Trial to Evaluate Efficacy of Pfizer's pan-HER and c-Met Targeted Therapies** – In January 2021, we announced a clinical trial collaboration with Sarah Cannon Research Institute and Pfizer to conduct a Phase II clinical trial. This open-label Phase II trial will evaluate the efficacy and safety of two Pfizer targeted therapies, Vizimpro (dacomitinib), a pan-HER inhibitor, and Xalkori (crizotinib), a c-Met inhibitor, in previously treated metastatic HER2-negative breast cancer patients selected with our CELSignia Multi-Pathway Activity Test. Based on the Sarah Cannon Research Institute's estimates of patient enrollment rates, interim results are expected 12-15 months after the protocol is activated and final results 12-15 months later. We expect enrollment to begin in the third quarter of 2021. The goal of the trial is to demonstrate that previously treated HER2-negative metastatic breast cancer patients who have hyperactive HER2 and c-Met signaling tumors, as identified by the CELSignia test, respond to treatment with Vizimpro in combination with Xalkori.
- **FACT-4 Clinical Trial to Evaluate Efficacy of Puma's HER2 Targeted Therapy** – In December 2020, we announced a clinical trial collaboration with Massachusetts General Hospital and Puma, a biopharmaceutical company, to conduct a Phase II clinical trial. This open-label Phase II trial will evaluate the efficacy and safety of Puma's drug, Nerlynx (neratinib), and Faslodex (fulvestrant), an AstraZeneca drug, in previously treated metastatic HR-positive (HR+), HER2-negative breast cancer patients selected with our CELSignia HER2 Pathway Activity Test. Based on Massachusetts General Hospital's estimates of patient enrollment rates, we expect to obtain interim results 12-15 months after the protocol is activated and final results 12 to 15 months later. We expect enrollment to begin in the third quarter of 2021. The goal of the trial is to demonstrate that previously treated HR+, HER2-negative metastatic breast cancer patients who have hyperactive HER2 signaling tumors, as identified by the CELSignia test, respond to treatment with Nerlynx in combination with Faslodex, a hormonal therapy that targets the estrogen receptor.

- **FACT-6 Clinical Trial to Evaluate Efficacy of Novartis's c-Met Inhibitor and Puma's pan-HER Inhibitor** – In March 2021, we announced a clinical trial collaboration with MD Anderson, Novartis AG, and Puma, to conduct a Phase I/II clinical trial. This open-label Phase I/II trial will evaluate the efficacy and safety of Novartis' c-Met inhibitor, Tabrecta (capmatinib), and Puma's pan-HER inhibitor, Nerlynx (neratinib), in previously treated metastatic HER2-negative breast cancer patients selected with our CELSignia Multi-Pathway Activity Test. Based on MD Anderson's estimates of patient enrollment rates, we expect to obtain interim results 12-15 months after the protocol is activated and final results 12-15 months later. We expect enrollment to begin in the third quarter of 2021. The goal of the trial is to demonstrate that previously treated HER2-negative metastatic breast cancer patients who have hyperactive HER2 and c-Met signaling tumors, as identified by the CELSignia test, respond to treatment with Tabrecta in combination with Nerlynx.

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Therapeutic (Rx) Product Development

Gedatolisib

Gedatolisib (PF-05212384) is a potent, reversible dual inhibitor that selectively targets PI3K and mTOR. Gedatolisib was originally developed by Wyeth and clinical development was continued by Pfizer after it acquired Wyeth. We exclusively licensed global rights to gedatolisib from Pfizer in April 2021. An on-going Phase 1b trial evaluating patients with ER+/HER2- metastatic breast cancer was initiated in 2016 and subsequently enrolled 138 patients. Patient enrollment for the four expansion arms of the trial is complete. Based on the favorable preliminary results reported to date from the Phase 1b trial, we intend to initiate, subject to feedback from the FDA, a Phase 2/3 clinical trial evaluating gedatolisib in combination with palbociclib and an endocrine therapy in patients with ER+/HER2- advanced or metastatic breast cancer in the first half of 2022.

Background

Breast cancer is the most prevalent cancer in women, accounting for 30% of all female cancers and 13% of cancer-related deaths in the United States. The National Cancer Institute estimated that approximately 270,000 new cases of breast cancer would be diagnosed in the United States in 2019, and approximately 42,000 breast cancer patients would die of the disease. Approximately 190,000, or 70%, of these new cases are for ER+/HER2- breast cancer.

Four different breast cancer subtypes are currently identified using molecular tests that determine the level of ER and HER2 expression. About 70% of breast cancers are ER+/HER2-, which is indicative of hormone dependency. Despite progress in treatment strategies, metastatic ER+/HER2- breast cancer (mBC) remains an incurable disease, with a median overall survival (OS) of three years and a five-year survival rate of 25%.

Four different classes of targeted therapies are currently used to treat ER+/HER2- tumors - endocrine-based therapies, CDK4/6 inhibitors, PI3K inhibitors and mTOR inhibitors. Each of the CDK4/6 inhibitors, PI3K inhibitors and mTOR inhibitors are generally used to respond to the related mechanisms of resistance to endocrine therapy, namely, activation of the CDK4/6, PI3K and mTOR pathways. These drugs generated revenues of over \$8 billion globally in 2020.

As specifically relates to gedatolisib, activation of the PI3K/mTOR pathway has been implicated in a wide variety of human cancers, involving either activating mutations, or other unknown drivers of pathway amplification. These include cancers of the breast, prostate, endometrial, colon, rectum, and lung, among others.

PI3K constitutes a lipid kinase family involved in the regulation of diverse cellular processes, including cell proliferation, survival, cytoskeletal organization, and glucose transport. Class I PI3Ks are of particular therapeutic interest. They are heterodimers, comprising a catalytic (p110 α , p110 β , p110 δ , or p110 γ) and a regulatory (p85 α , p55 α , p50 α , p85 β , p55 γ , or p101) subunit. Oncogenic PI3K signaling is activated by cell-surface receptors such as receptor tyrosine kinases, G-protein-coupled receptors, and also by well-known oncogenic proteins such as Ras.

Activities associated with PI3K involve complex essential cell regulatory mechanisms including feedforward and feedback signaling loops. Overactivation of the pathway is frequently present in human malignancies and plays a key role in cancer progression. Each of the four catalytic isoforms of class I PI3K preferentially mediate signal transduction and tumor cell survival based on the type of malignancy and the genetic or epigenetic alterations an individual patient harbors. For example, studies have demonstrated the p110 α

catalytic isoform is necessary for the growth of tumors driven by PIK3CA mutations and/or oncogenic RAS and receptor tyrosine kinases; the p110 β catalytic isoform mediates tumorigenesis arising from the loss of the dephosphorylase activity of PTEN; and the p110 δ catalytic isoform is highly expressed in leukocytes, making it a desirable target for inhibition in the treatment of hematologic malignancies. Due to the multiple subcellular locations, activities, and importance of the different PI3K complexes in regulating many types of cancer cell proliferation, control of PI3K activity is an important target in cancer therapy.

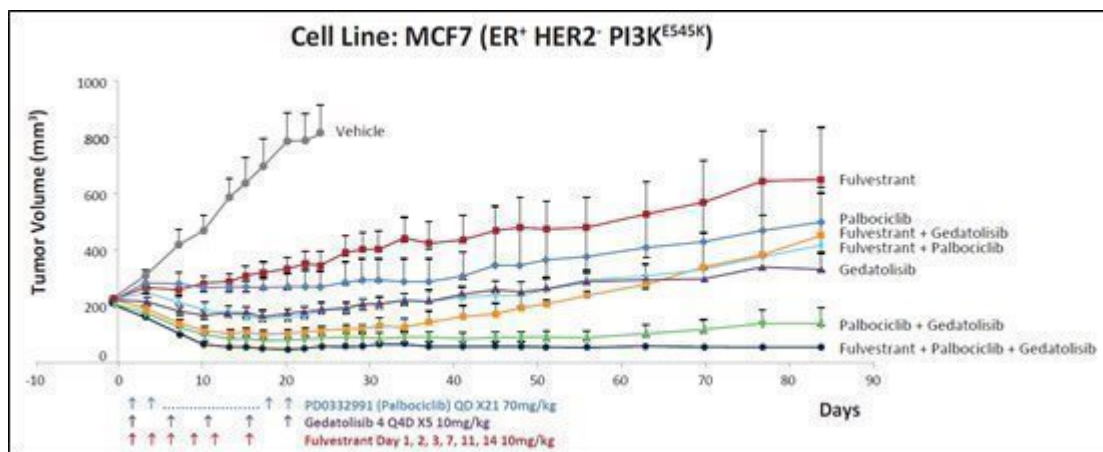
mTOR is as a critical effector in cell-signaling pathways commonly dysregulated in human cancers. The mTOR signaling pathway integrates both intracellular and extracellular signals and serves as a central regulator of cell metabolism, growth, proliferation, and survival. mTOR is a serine/threonine protein kinase, a downstream effector of PI3K, and regulated by hormones, growth factors, and nutrients, that is contained in two functionally distinct protein assemblies: mTOR complex 1 (mTORC1) and mTOR complex 2 (mTORC2). mTORC1 belongs to a complex network of regulatory feedback loops, and once certain levels of activation are reached, is normally responsible for limiting the proliferative signals transmitted by upstream effectors such as PI3K/AKT activity. Equally complex mTORC2 regulates AKT phosphorylation, GSK3 β , and control over glycolysis, and participates in organizing the cellular actin cytoskeleton. In addition, mTORC1 activation leads to the direct reduction of mTORC2 activity and mTOR can activate the functional domain of the ER, leading to ligand-independent hormone receptor activation. In cancer, dysfunctional signaling leads to various constitutive activities of mTOR complexes, making mTOR a good therapeutic target.

PI3K/mTOR as Resistance Mechanism to Endocrine and CDK4/6 Inhibitors

The upregulation of the PI3K/AKT/mTOR pathway promotes hormone dependent and independent ER transcriptional activity, which contributes to endocrine resistance, leading to tumor cell growth, survival, motility, and metabolism. It has also been demonstrated in vivo that PI3K and mTOR inhibition can restore sensitivity to endocrine therapy, providing a strong rationale for the combination of the two therapies.

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In addition, the PI3K/AKT/mTOR pathway, like other mitogenic pathways, can also promote the activities of cyclin D and CDK4/6 to drive proliferative cell cycling. Internal preclinical studies conducted by Pfizer provided evidence in cell-line xenograft models that the combination of PI3K and CDK4/6 inhibitors may overcome both intrinsic and adaptive resistance to endocrine therapy, leading to tumor regressions. In an MCF7 xenograft model (ER+/HER2-/PIK3CA mutant) the combination of gedatolisib with palbociclib and fulvestrant led to durable tumor regressions. Importantly, tumors regressed to minimal volumes within 20 days of triplet therapy, and continued to remain dormant, without further therapy, for up to 90 days.



Advantages of Gedatolisib over other PI3K and mTOR inhibitors

The important role the PI3K/AKT/mTOR pathway plays in cancer has led to significant investment in the development of many different PI3K and mTOR inhibitors for solid tumors. However, developing efficacious and well-tolerated therapies that target this pathway has been challenging. This reflects the inherent adaptability and complexity of the PI3K pathway, where numerous feedforward and feedback loops, crosstalk with other pathways, and compensatory pathways enable resistance to PI3K inhibition. Another major hurdle for the development of PI3K pathway inhibitors has been the inability to achieve optimal drug-target blockade in tumors while

avoiding undue toxicities in patients. These challenges may explain why PI3K and mTOR inhibitors have not yielded the outstanding clinical activity many researchers expected.

We believe there is significant potential for gedatolisib to address previously treated breast cancer tumors and has the potential to be used in other tumor types where the PI3K/AKT/mTOR pathway is either: i) driving tumorigenesis directly; ii) cooperating with other dysregulated signaling pathways; or iii) a mechanism of resistance to other drug therapies.

As a result, we believe gedatolisib's unique mechanism of action and intravenous formulation offer distinct advantages over currently approved and investigational therapies that target PI3K or mTOR alone or together.

- **Overcomes drug resistance that can occur with isoform-specific PI3K inhibitors.**

Gedatolisib is a pan-class I isoform PI3K inhibitor with low nanomolar potency for the p110 α , p110 β , p110 γ , and p110 δ isoforms. Each isoform is known to preferentially affect different signal transduction events that involve tumor cell survival, depending upon the aberrations associated with the linked pathway. A pan-PI3K inhibitor can thus treat tumors harboring abnormalities that signal through different PI3K isoforms, which would potentially induce anti-tumor activity in a broader population of patients than an isoform-specific PI3K inhibitor. In addition, it has been reported that inhibition of one PI3K isoform may be offset by the increased activity of the other isoforms through different adaptive mechanisms. Inhibiting all four PI3K isoforms, as gedatolisib does, can thus prevent the confounding effect of isoform interaction that may occur with isoform-specific PI3K inhibitors.

- **Overcomes paradoxical activation of PI3K induced by mTOR inhibition.**

As a potent inhibitor of mTOR, in addition to PI3K, gedatolisib, inhibits the PI3K/AKT/mTOR pathway both upstream and downstream of AKT. Furthermore, it has been demonstrated that the PI3K pathway is activated following selective mTOR inhibition by relief of normal feedback regulatory mechanisms, thus providing a compelling rationale for simultaneous inhibition of PI3K and mTOR.

- **Better tolerated by patients than oral PI3K and mTOR drugs.**

Gedatolisib is administered intravenously (IV) once weekly or on a four-week cycle of three weeks-on, one week-off, in contrast to the orally administered pan-PI3K or dual PI3K/mTOR inhibitors that are no longer being clinically developed. Oral pan-PI3K or PI3K/mTOR inhibitors have repeatedly been found to induce significant side effects that were not well tolerated by patients. This typically leads to a high proportion of patients requiring dose reductions or treatment discontinuation. The challenging toxicity profile of these drug candidates ultimately played a significant role in the decisions to halt their development, despite showing promising efficacy. By contrast, gedatolisib stabilizes at lower concentration levels in plasma compared to orally administered PI3K inhibitors, resulting in less toxicity, while maintaining concentrations sufficient to inhibit PI3K/AKT/mTOR signaling.

Isoform-specific PI3K inhibitors administered orally were developed to reduce toxicities in patients. While the range of toxicities associated with isoform-specific inhibitors is narrower than oral pan-PI3K or PI3K/mTOR inhibitors, administering them orally on a continuous basis still leads to challenging toxicities. The experience with an FDA approved oral p110- α specific inhibitor, Piqray, illustrates the challenge. In its Phase 3 pivotal trial Piqray was found to induce a Grade 3 or 4 adverse event (AE) related to hyperglycemia in 39% of patients evaluated. In addition, 26% of patients discontinued treatment. By contrast, in the 103-patient dose expansion portion of the Phase 1b clinical trial with gedatolisib, only 7% of patients experienced Grade 3 or 4 hyperglycemia and less than 10% discontinued treatment.

As of January 11, 2021, 492 patients with solid tumors have received gedatolisib in eight clinical trials sponsored by Pfizer. Of the 492 patients, 129 were treated with gedatolisib as a single agent in three clinical trials. The remaining 363 patients received gedatolisib in combination with other anti-cancer agents in five clinical trials. Additional patients received gedatolisib in combination with other anti-cancer agents in nine investigator sponsored clinical trials.

Phase 1 First-in-Human Study

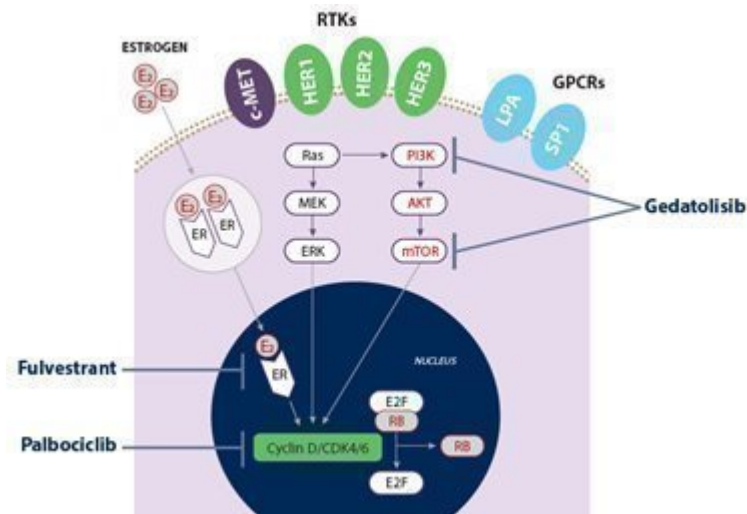
Pfizer conducted a Phase 1, open-label, dose-escalation first-in human study of single-agent gedatolisib in patients with advanced solid tumors. The primary objective of Part 1 of the study was to determine the safety, tolerability, and maximum tolerated dose (MTD) of single-agent gedatolisib administered once weekly as an intravenous (IV) infusion. Seventy-seven patients with advanced solid tumors received doses of gedatolisib and the MTD was determined to be 154 mg IV once weekly (n = 42). Subsequent analysis determined that the recommended Phase 2 dose could be increased to 180 mg IV once weekly.

At the MTD, the majority of patients enrolled in the MTD group experienced only grade 1 treatment-related adverse events (AEs). Grade 3 treatment-related adverse events were noted in 23.8% of patients, and the most frequently reported included mucosal inflammation and stomatitis (7.1%), increased alternative lengthening of telomeres (ALT) (7.1%), and increased aspartate aminotransferase (AST) (4.8%). No treatment-related AEs of grade 4 or 5 severity were reported at any dose level.

Phase 1b ER+/HER2- mBC Clinical Trial Results (preliminary)

In 2016, Pfizer initiated a Phase 1b trial dose-finding trial with an expansion portion for safety and efficacy to evaluate gedatolisib when added to either the standard doses of palbociclib plus letrozole or palbociclib plus fulvestrant in patients with ER+/HER2- metastatic breast cancer. PI3K mutation status was not used as an eligibility criterion. Patient enrollment for the trial is complete.

The illustration below depicts how the combination of gedatolisib, palbociclib, and fulvestrant is intended to simultaneously block interdependent ER, PI3K, mTOR & CDK signaling pathways in ER+ breast cancer to address ER and CDKi resistance mechanisms.



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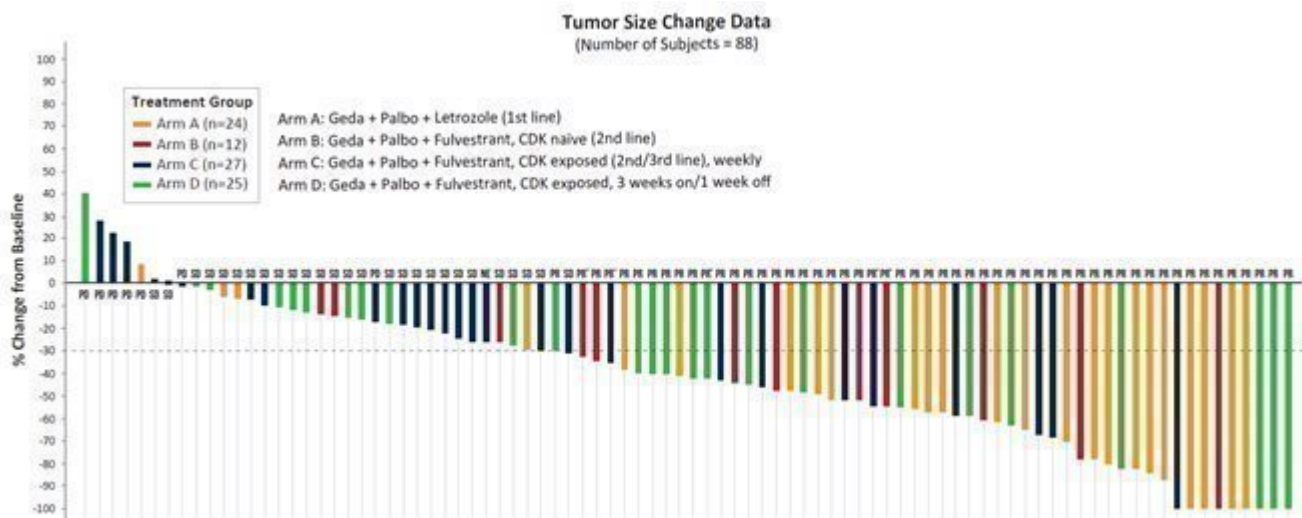
A total of 138 patients with ER+/HER2- metastatic breast cancer were dosed in the clinical trial.

- 35 patients were enrolled in two dose escalation arms to evaluate the safety and tolerability and determine the MTD of gedatolisib when used in combination with the standard doses of palbociclib and endocrine therapies. The MTD was determined to be 180 mg administered intravenously once weekly.
- 103 patients were enrolled in one of four expansion arms (A, B, C, D) to determine if the triplet combination of gedatolisib plus palbociclib and letrozole or gedatolisib plus palbociclib and fulvestrant produced a superior objective response (OR), compared to historical control data of the doublet combination (palbociclib plus endocrine therapy). All patients received gedatolisib in combination with standard doses of palbociclib and endocrine therapy (either letrozole or fulvestrant). In Arms A, B, and C, patients received an intravenous dose of 180 mg of gedatolisib once weekly. In Arm D, patients received an intravenous dose of 180 mg of gedatolisib on a four-week cycle of three weeks-on, one week-off. Objective response was determined using Response Evaluation Criteria in Solid Tumors v1.0, or RECIST v1.0.

- **Arm A:** mBC with progression and no prior endocrine-based systemic therapy or a CDK4/6 inhibitor in the metastatic setting. First-line endocrine-based therapy for metastatic disease (CDK4/6 treatment naive).
- **Arm B:** mBC with progression during one or two prior endocrine-based systemic therapy in the metastatic setting, with no prior therapy with any CDK inhibitor. Second- or third-line endocrine-based therapy for metastatic disease.
- **Arm C:** mBC with progression during one or two prior endocrine-based systemic therapies in the metastatic setting and following prior therapy with a CDK inhibitor. Second- or third-line endocrine-based therapy for metastatic disease.
- **Arm D:** mBC having progressed on a CDK inhibitor in combination with endocrine therapy as the most recent regimen for metastatic disease. Second- or third-line endocrine-based therapy for metastatic disease.

A preliminary analysis for the 103 patients enrolled in the expansion portion of the Phase 1b clinical trial, as of the database cutoff date of January 11, 2021, showed:

- Efficacy analysis for all arms in aggregate:
 - 60% objective response rate (ORR): 53 of the 88 evaluable patients had either a confirmed or unconfirmed partial response, or PR (48 confirmed, 5 unconfirmed).
 - 75% clinical benefit rate (CBR): 66 of the 88 evaluable patients had either a confirmed PR or had stable disease for 24 weeks.
- Best responses, as measured by RECIST v1.0, are shown in the following chart. The dotted line represents the cutoff for PR (defined as a 30% reduction from baseline).



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- Preliminary safety analysis:
 - For all arms in aggregate, all patients experienced at least one Grade 1 or Grade 2 treatment-emergent adverse event. The most commonly reported adverse events regardless of grade and occurring in at least 30% of patients included stomatitis (81%), neutropenia (80%), nausea (75%), fatigue (68%), dysgeusia (46%), vomiting (45%), anemia (40%), diarrhea (34%), decreased appetite (32%), leukopenia (32%).
 - For all arms in aggregate, the Grade 3 and 4 treatment-emergent adverse events occurring in at least 20% of patients were neutropenia (67%), stomatitis (27%) and rash (20%). Neutropenia is a known class effect of CDK4/6 inhibitors.

Stomatitis was reversible in most patients with a steroidal mouth rinse. All grades of treatment-related adverse events related to hyperglycemia was reported in 22% of patients; Grade 3 or 4 hyperglycemia was reported in 7% of patients. Gedatolisib was discontinued in 10% of patients.

- For the patients in Arm D, who received the recommended phase two dose, Grade 3 and 4 treatment-emergent adverse events occurring in at least 20% of patients were neutropenia (67%) stomatitis and (22%). All grades of treatment-related adverse events related to hyperglycemia was reported in 22% of patients; Grade 3 or 4 hyperglycemia was reported in 7% of patients. Gedatolisib was discontinued in 7% of patients.
- As of the cutoff date, 22 patients were continuing to receive gedatolisib in combination with the other study drugs, 17 of whom have been on study treatment for more than two years.

- Preliminary best overall response data for each arm is presented in the table below:

Arm (evaluable patients)	A (N=24)	B (N=12)	C (N=27)	D (N=25)
Patients	1L: CDKi-Naïve	2L+: CDKi-naïve	2L/3L: CDKi-pretreated	2L/3L: Immediately prior CDKi
Overall Response Rate (evaluable patients)	83%	75% ¹	33% ²	60% ³
Clinical Benefit Rate (evaluable patients)	92%	92%	48%	76%

1. Arm A: 20 of the 24 evaluable patients had a confirmed PR.
2. Arm B: 9 of the 12 evaluable patients had either a confirmed PR or unconfirmed PR (7 confirmed PR, 2 unconfirmed PR).
3. Arm C: 9 of the 27 evaluable patients had either a confirmed PR or unconfirmed PR (7 confirmed PR, 2 unconfirmed PR).
4. Arm D: 15 of the 25 evaluable patients had either a confirmed PR or unconfirmed PR (14 confirmed PR, 1 unconfirmed PR).

- Preliminary progression free survival (PFS) data for each arm is presented in the table below:

Arm (enrolled patients)	A (N=31)	B (N=13)	C (N=32)	D (N=27)
Median PFS (months) (95% CI)	>29 (Not Yet Reached)	11.9 (3.7, NR)	5.1 (3.4, 7.5)	13.2 (9.0, 16.7)

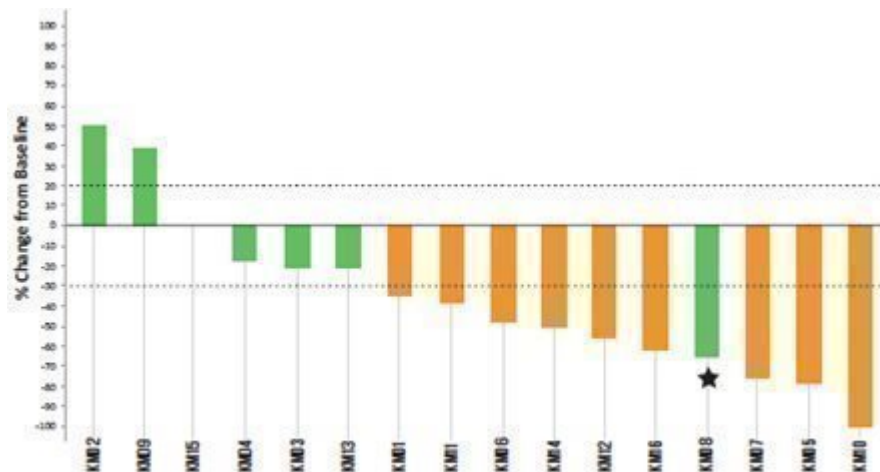
In light of the preliminary results reported to date from the Phase 1b trial, we intend to initiate, subject to feedback from the FDA, a Phase 2/3 clinical trial evaluating gedatolisib in combination with palbociclib and an endocrine therapy in patients with ER+/HER2- advanced or metastatic breast cancer in the first half of 2022.

We expect to use the CELsignia PI3K Activity Test to help support development of gedatolisib for breast cancer indications. Our internal studies demonstrate how measurement of PI3K-involved signaling may provide a sensitive and specific method of identifying patients most likely to benefit from PI3K inhibitors. We believe CELsignia tests uniquely enable us to pursue indications simultaneously for unselected patient populations and CELsignia selected patient sub-groups. This approach can greatly reduce the risk of pursuing an indication for a large, but unselected patient population, as we plan to do for the initial gedatolisib indication. By combining the capabilities of CELsignia PI3K Activity Test with a potent pan-PI3K/mTOR inhibitor like gedatolisib, we believe we are uniquely suited to maximize the probability of obtaining regulatory approval to market gedatolisib.

The Korean Cancer Study Group sponsored a Phase 2 pilot clinical trial to evaluate gedatolisib combined with a trastuzumab biosimilar (Herzuma®), in patients with HER2+/PIK3CA+ metastatic breast cancers whose disease had progressed after treatment with three or more prior HER2 targeted therapy regimens. The clinical trial commenced in December 2019 and interim efficacy data from the first 16 patients enrolled was presented at the San Antonio Breast Cancer Symposium in December 2020. Patients received a trastuzumab biosimilar (8 mg/kg IV for 1st cycle loading dose, and then 6 mg/kg IV every 3 weeks) plus gedatolisib (180 mg, weekly IV). The primary endpoint was objective response, a reduction of at least 30% in tumor volume by RECIST v1.1.

As of a data cutoff date of October 30, 2020, nine of 16 patients achieved a partial response, an ORR of 56%, and four patients had stable disease. Thirteen of 16 patients thus received either a partial response or stable disease, resulting in a clinical benefit rate of 81%. Best responses are shown in the following chart. The dotted lines represent the cutoff for progressive disease (>20% tumor growth) and for partial response (>30% tumor regression).

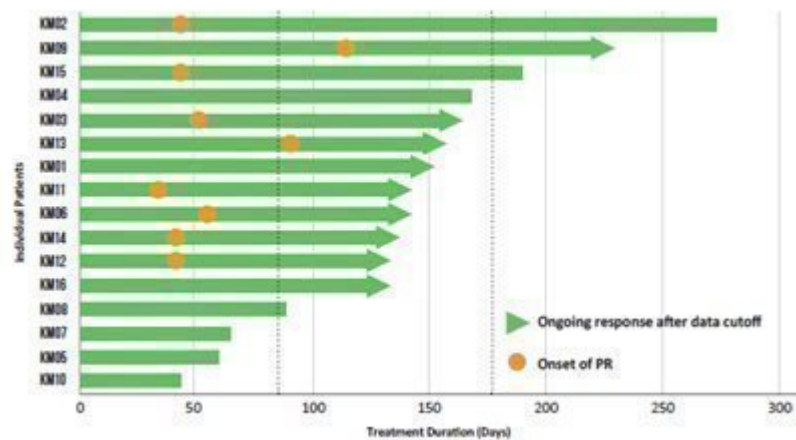
Best Response



* Patient whose target lesion decreased by 63% but a new leptomeningeal seeding occurred.

The duration of treatment for the 16 patients evaluated is shown in the chart below. As of the October 30, 2020 data cutoff, 16 patients (80%) remained on therapy. Four patients discontinued treatment, one due to disease progression, one due to an adverse event of Grade 1 diarrhea, one participant decision, and one patient being unable to undergo the required MRI imaging due to a titanium rod implant from non-treatment related worsening of scoliosis. At the time of data cut-off, the median time on treatment for these 16 patients was 10.1 cycles (approximately 10 months) and all 10 patients who had achieved an objective response remained on therapy assessment. At the time of the analysis, nine patients had a continuing response. The dashed lines show the response at 3 months and 6 months.

Duration of Treatment



Impact of COVID-19 on our Business

Health and Safety

To help protect the health and safety of our employees, suppliers and collaborators, we took proactive, aggressive action from the earliest signs of the outbreak. We enacted rigorous safety measures in our laboratory and administrative offices, including implementing social distancing protocols, allowing working from home for those employees that do not need to be physically present in a lab to perform their work, suspending travel, implementing temperature checks at the entrances to our facilities, extensively and frequently disinfecting our workspaces and providing masks to those employees who must be physically present. We expect to continue with these measures until the COVID-19 pandemic is better contained and we may take further actions as government authorities require or recommend or as we determine to be in the best interests of our employees, suppliers, and collaborators.

Clinical Trials and Collaborations

As a result of the COVID-19 pandemic, governmental authorities implemented numerous and constantly evolving measures to try to contain the virus, such as travel bans and restrictions, limits on gatherings, quarantines, shelter-in-place orders, and business shutdowns. While many of these measures have been relaxed in recent months, new variants of the coronavirus, such as the delta variant, appear likely to cause new or former protective measures to be reconsidered. As we continue to advance our clinical trial collaborations, we are in close contact with our current clinical sponsors, and principal investigators, as well as prospective pharmaceutical company and clinical collaborators, to assess the impact of COVID-19 on our trial enrollment timelines and collaboration discussions. Based on delays in the enrollment of patients in our ongoing clinical trials due to the pandemic, we now expect interim results from the FACT-1 and FACT-2 trials to be delayed until late 2021 or early 2022 and final results approximately nine months later. As the impact of COVID-19 on our industry becomes clearer, we may need to reassess the timing of our anticipated clinical milestones. Prospective clinical trial collaborations with pharmaceutical companies and sponsors may also be delayed but the impact on the timing of finalizing agreements is not yet known.

Research and Development

While our facility currently remains operational, the evolving measures to try to contain the virus have impacted and may further impact our workforce and operations, as well as those of our vendors and suppliers. Our laboratory remains operational as of this date, but, in response to the COVID-19 pandemic, we have implemented protective policies that reduce the number of research and development staff operating in our laboratory at any one time. However, in light of the focus of healthcare providers and hospitals on fighting the virus, several of the clinical sites that provide us tumor tissue for research have halted this service, reducing the number of new tumor tissue specimens we would typically expect to receive. These various constraints may slow or diminish our research and development activities, particularly if the pandemic continues to experience rising infections from the delta variant of the coronavirus or otherwise. In addition, cancer research-related industry meetings, such as the American Association for Cancer Research (AACR), were previously delayed for several months and could be again in the future as a result of the virus. So far, our submissions to present research results at these meetings have been accepted, but the release of the results have been postponed in conjunction with the delayed meeting schedules. We cannot be certain as to whether these types of delays will continue and what the impact will be on our ability to present research results in the future.

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Results of Operations

We have not generated any revenue from sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not and have never been profitable and have incurred losses in each period since our inception in 2012. For the three months ended June 30, 2021 and 2020, we reported a net loss of approximately \$14.0 million and \$2.2 million, respectively, and for the six months ended June 30, 2021 and 2020, we reported a net loss of approximately \$16.8 million and \$4.4 million, respectively. As of June 30, 2021, we had an accumulated deficit of approximately \$43.1 million. As of June 30, 2021, we had cash and cash equivalents of approximately \$41.6 million.

Components of Operating Results

Revenue

To date, we have not generated any revenue. Initially, our ability to generate revenue will depend primarily upon our ability to obtain partnership agreements with pharmaceutical companies to provide companion diagnostics for such pharmaceutical partners' existing or investigational targeted therapies. We expect these partnerships to generate significant revenue from the sale of tests to identify patients eligible for clinical trials, from milestone payments, and, potentially, from royalties on the incremental drug revenues our tests enable. Once a new drug indication is received that requires use of our companion diagnostic to identify eligible patients, we expect to generate revenues from sales of tests to treating physicians. With the execution of the Pfizer license agreement in April 2021, whereby we acquired exclusive world-wide licensing rights to develop and commercialize gedatolisib, we expect to conduct clinical trials to support potential regulatory approval to market gedatolisib. If we obtain regulatory approvals to market gedatolisib, we expect to generate revenue from sales of the drug for the treatment of breast cancer patients.

Research and Development

Since our inception, we have primarily focused on research and development of our CELsignia platform, development and validation of our CELsignia tests, and research related to the discovery of new cancer sub-types. Beginning in April 2021, we are also focusing on development of gedatolisib, a PI3K/mTOR targeted therapy. Research and development expenses primarily include:

- employee-related expenses related to our research and development activities, including salaries, benefits, recruiting, travel and stock-based compensation expenses;
- laboratory supplies;
- consulting fees paid to third parties;
- clinical trial costs;
- facilities expenses; and
- legal costs associated with patent applications.

Internal and external research and development costs are expensed as they are incurred. As we initiate clinical trials to evaluate efficacy of targeted therapies in cancer patients selected with one of our CELsignia tests and to develop gedatolisib, the proportion of research and development expenses allocated to external spending will grow at a faster rate than expenses allocated to internal expenses.

General and Administrative

General and administrative expenses consist primarily of salaries, benefits and stock-based compensation related to our executive, finance and support functions. Other general and administrative expenses include professional fees for auditing, tax, and legal services associated with being a public company, director and officer insurance, investor relations and travel expenses for our general and administrative personnel.

Sales and Marketing

Sales and marketing expenses consist primarily of professional and consulting fees related to these functions. To date, we have incurred immaterial sales and marketing expenses as we continue to focus primarily on the development of our CELsignia platform and corresponding CELsignia tests. We would expect to begin to incur increased sales and marketing expenses in anticipation of the commercialization of our first CELsignia tests and the commercialization of our first drug, gedatolisib. These increased expenses are

expected to include payroll-related costs as we add employees in the commercial departments, costs related to the initiation and operation of our sales and distribution network and marketing related costs.

Interest Expense

Interest expense is primarily due to a loan agreement and finance lease obligations.

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Interest Income

Interest income consists of interest income earned on our cash, cash equivalents, and investment balances.

Results of Operations

	Three Months Ended		Increase (Decrease)	
	June 30,		\$	Percent Change
	2021	2020		
Statements of Operations Data:				
Operating expenses:				
Research and development	\$ 13,070,108	\$ 1,766,227	\$ 11,303,881	640%
General and administrative	573,360	447,714	125,646	28
Total operating expenses	13,643,468	2,213,941	11,429,527	516
Loss from operations	(13,643,468)	(2,213,941)	(11,429,527)	516
Other income (expense)				
Interest expense	(391,187)	(31)	(391,156)	n/a
Interest income	1,803	11,983	(10,180)	(85)
Loss on sale of fixed assets	-	-	-	n/a
Other income (expense), net	(389,384)	11,952	(401,336)	(3,358)
Net loss before income taxes	(14,032,852)	(2,201,989)	(11,830,863)	537
Income tax benefits	-	-	-	-
Net loss	\$(14,032,852)	\$(2,201,989)	\$(11,830,863)	537%

	Six Months Ended		Increase (Decrease)	
	June 30,		\$	Percent Change
	2021	2020		
Statements of Operations Data:				
Operating expenses:				
Research and development	\$ 15,306,451	\$ 3,613,641	\$ 11,692,810	324%
General and administrative	1,128,787	911,113	217,674	24
Total operating expenses	16,435,238	4,524,754	11,910,484	263
Loss from operations	(16,435,238)	(4,524,754)	(11,910,484)	263
Other income (expense)				
Interest expense	(391,210)	(64)	(391,146)	n/a
Interest income	2,191	75,834	(73,643)	(97)
Gain on sale of fixed assets	(263)	-	(263)	n/a
Other income (expense), net	(389,282)	75,770	(465,052)	(614)
Net loss before income taxes	(16,824,520)	(4,448,984)	(12,375,536)	278
Income tax benefits	-	-	-	-
Net loss	\$(16,824,520)	\$(4,448,984)	\$(12,375,536)	278%

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Research and Development

Our research and development expenses for the three months ended June 30, 2021 were approximately \$13.07 million, representing an increase of approximately \$11.30 million, or 640%, compared to the same period in 2020. The increase primarily resulted from a \$10.0 million upfront license fee related to the execution of the Pfizer license agreement, which included \$5.0 million of non-cash expense for the issuance of common stock. Compensation related expenses accounted for a \$0.61 million increase, including approximately \$0.06 million of non-cash stock-based compensation, to support development of our CELsignia platform and the development of gedatolisib. In addition, other research and development expenses increased \$0.69 million due to clinical validation and laboratory studies, legal fees related to patent prosecution and operational and business development activities.

Our research and development expenses for the six months ended June 30, 2021 were approximately \$15.31 million, representing an increase of approximately \$11.69 million, or 324%, compared to the same period in 2020. The increase primarily resulted from a \$10.0 million upfront license fee related to the execution of the Pfizer license agreement, which included \$5.0 million of non-cash expense for the issuance of common stock. Compensation related expenses accounted for a \$0.71 million increase, including approximately \$0.03 million of non-cash stock-based compensation, to support development of our CELsignia platform and the development of gedatolisib. In addition, other research and development expenses increased \$0.98 million due to clinical validation and laboratory studies, legal fees related to patent prosecution and operational and business development activities.

Conducting a significant amount of research and development is central to our business model. We plan to increase our research and development expenses for the foreseeable future as we seek to discover new cancer sub-types, develop and validate additional CELsignia tests to diagnose such sub-types and develop gedatolisib. We also expect to incur increased expenses to support companion diagnostic business development activities with pharmaceutical companies as we develop additional CELsignia tests and initiate a clinical trial for gedatolisib.

General and Administrative

Our general and administrative expenses for the three months ended June 30, 2021 were approximately \$0.57 million, representing an increase of approximately \$0.13 million, or 28%, compared to the same period in 2020. The increase primarily resulted from a \$0.05 million increase in non-cash stock-based compensation. In addition, other general and administrative expenses increased \$0.08 million due to professional fees associated with being a public company and director and officer insurance.

Our general and administrative expenses for the six months ended June 30, 2021 were approximately \$1.13 million, representing an increase of approximately \$0.22 million, or 24%, compared to the same period in 2020. The increase primarily resulted from a \$0.08 million increase in non-cash stock-based compensation. In addition, other general and administrative expenses increased \$0.14 million due to professional fees associated with being a public company and director and officer insurance.

We anticipate that our general and administrative expenses will increase in future periods, reflecting both increased costs in connection with the potential future commercialization of CELsignia tests and gedatolisib, an expanding infrastructure, and increased professional fees associated with being a public company.

Interest Expense

Interest expense for the three months and six months ended June 30, 2021 was \$0.4 million and represents an increase of \$0.4 million compared to the same periods in 2020. The increase is due to the loan agreement that was executed in April 2021 and includes \$0.17 million of non-cash interest expense.

Interest Income

Interest income for the three months and six months ended June 30, 2021 represents a decrease of approximately \$0.01 and \$0.07 million, respectively, compared to the same period in 2020. This decrease was primarily the result of lower market interest rates.

Liquidity and Capital Resources

Since our inception, we have incurred losses and cumulative negative cash flows from operations. Through June 30, 2021, we have raised capital of approximately \$13.7 million and \$7.5 million through private placements of common equity and unsecured convertible notes, respectively. On September 22, 2017, we closed on the initial public offering of our common stock, which generated approximately \$23.3 million of additional cash after taking into account underwriting discounts and commissions and offering expenses. On June 5, 2020, we entered into an At Market Issuance Sales Agreement with B. Riley, FBR, Inc (the “ATM Agreement”). The ATM Agreement allowed us to sell shares of common stock up to an aggregate offering price of \$10.0 million. Through June 30, 2021, we generated approximately \$0.09 million of additional cash through sales pursuant to the ATM Agreement, after taking into account commissions and offering expenses. On February 26, 2021, we completed a follow-on offering of our common stock, which generated approximately \$25.8 million of additional cash after taking into account underwriting discounts and offering expenses. In conjunction with the follow-on offering, the ATM Agreement was terminated. On April 8, 2021, we entered into a loan agreement with Innovatus Life Sciences Lending Fund I, LP (“Innovatus”), whereby Innovatus agreed to loan up to \$25 million in three tranches consisting of (i) a \$15.0 million non-contingent term A loan that was funded on April 8, 2021, (ii) a \$5 million term B loan to be funded upon our request no later than March 31, 2022, and (iii) a \$5 million term C loan to be funded upon our request no later than March 31, 2023. Funding of the term B and C loan is subject to our ability to achieve certain milestones.

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Cash from these capital raising activities has been our primary source of funds for our operations since inception. As of June 30, 2021, our cash and cash equivalents were approximately \$41.6 million, and we had an accumulated deficit of approximately \$43.1 million. Our cash and cash equivalents does not include the proceeds of a follow-on offering that we completed on July 1, 2021, whereby we generated gross proceeds of approximately \$56.3 million before deducting underwriting discounts of approximately \$3.4 million and offering expenses of approximately \$0.1 million.

We expect that our research and development and general and administrative expenses will increase as we continue to develop our CELsignia platform and additional CELsignia tests, conduct research related to the discovery of new cancer sub-types, conduct clinical trials, develop gedatolisib and pursue other business development activities. We would also expect to incur sales and marketing expenses as we commercialize our CELsignia tests and gedatolisib. We expect to use cash on hand to fund our research and development expenses, capital expenditures, working capital, sales and marketing expenses, and general corporate expenses, as well as for the increased costs associated with being a public company.

Based on our current business plan, we believe that our current cash on hand will provide sufficient cash to finance operations and pay obligations when due for at least the next twelve months.

We may seek to raise additional capital to expand our business, pursue strategic investments, and take advantage of financing or other opportunities that we believe to be in the best interests of the Company and our stockholders. Additional capital may be raised through the sale of common or preferred equity or convertible debt securities, entry into debt facilities or other third-party funding arrangements. The sale of equity and convertible debt securities may result in dilution to our stockholders and those securities may have rights senior to those of our common shares. Agreements entered into in connection with such capital raising activities could contain covenants that would restrict our operations or require us to relinquish certain rights. Additional capital may not be available on reasonable terms, or at all.

Cash Flows

	Six Months Ended	
	June 30,	
	2021	2020
	(unaudited)	
Net cash provided by (used in):		
Operating activities	\$(10,139,253)	\$ (3,389,646)
Investing activities	(57,397)	(66,589)
Financing activities	40,197,362	151,792
Net increase (decrease) in cash and cash equivalents	<u>\$ 30,000,712</u>	<u>\$ (3,304,443)</u>

Operating Activities

Net cash used in operating activities was approximately \$10.14 million for the six months ended June 30, 2021 and consisted primarily of a net loss of approximately \$16.82 million, offset by non-cash expense items of approximately \$6.34 million and working capital changes of \$0.34 million. Non-cash expense items of approximately \$6.34 million primarily consisted of \$5.0 million for issuance of common stock related to a license agreement, \$0.99 million of stock-based compensation expense, depreciation expense of \$0.18 million and non-cash interest expense of \$0.17 million. The approximately \$0.34 million of working capital changes was primarily due to an increase in accounts payable and a decrease in accrued expenses. The net cash used in operating activities was approximately \$3.39 million for the six months ended June 30, 2020 and consisted primarily of a net loss of approximately \$4.45 million and working capital changes of approximately \$0.02 million, offset by non-cash expense items of approximately \$1.08 million. Non-cash expense items of approximately \$1.08 million primarily consisted of \$0.89 million of stock-based compensation expense and depreciation expense of \$0.19 million.

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Investing Activities

Net cash used in investing activities for the six months ended June 30, 2021 was approximately \$0.06 million and consisted of purchases of property and equipment. Net cash used in investing activities for the six months ended June 30, 2020 was approximately \$0.07 million and consisted of purchases of property and equipment.

Financing Activities

Net cash provided by financing activities for the six months ended June 30, 2021 was approximately \$40.20 million. The \$40.20 million primarily consisted of \$25.77 million from net proceeds from the sale of shares of our common stock through a follow-on offering and \$14.35 million from net proceeds related to the closing of a loan agreement. The remaining \$0.08 million was the result of proceeds from the exercise of common stock warrants and employee stock options and proceeds from employee stock purchases. The net cash used by financing activities for the six months ended June 30, 2020 was approximately \$0.15 million and primarily reflects net proceeds from the sale of shares of our common stock through the ATM Agreement and employee stock purchases.

Off-Balance Sheet Arrangements

We do not currently have any off-balance sheet arrangements as defined in Item 303(a)(4) of Regulation S-K.

Recent Accounting Pronouncements

From time-to-time new accounting pronouncements are issued by the Financial Accounting Standards Board or other standard setting bodies and adopted by us as of the specified effective date. Unless otherwise discussed in Note 2 to our unaudited condensed financial statements included in Item 1 of Part I of this Quarterly Report, we believe that the impact of recently issued standards that are not yet effective will not have a material impact on our financial position or results of operations upon adoption.

Critical Accounting Policies and Use of Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our unaudited condensed financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses during the reporting periods. These items are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances; the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ materially from these estimates.

Our significant accounting policies are more fully described in Note 2 to our unaudited condensed financial statements included in Item 1 of Part I of this Quarterly Report.

Private Securities Litigation Reform Act

The Private Securities Litigation Reform Act of 1995 provides a “safe harbor” for forward-looking statements. Such forward-looking information is included in this Quarterly Report and in other materials filed or to be filed by us with the SEC (as well as information included in oral statements or other written statements made or to be made by us). Forward-looking statements include all statements based on future expectations. This Quarterly Report contains forward-looking statements that involve risks and uncertainties including, but not limited to, (i) our clinical trial plans and the estimated costs for such trials, including the timing of launching a Phase 2/3 clinical trial for gedatolisib; (ii) our expectations with respect to costs and timelines to develop, validate and launch CELSignia tests and to continue to develop gedatolisib; (iii) our beliefs related to the perceived advantages of our CELSignia tests compared to traditional molecular or other diagnostic tests; (iv) the expected benefits of gedatolisib; (v) our expectations regarding the timeline of patient enrollment and results from clinical trials, including the existing clinical trial for gedatolisib; (vi) the future payments that may be owned to Pfizer under the License Agreement; (vii) our expectations regarding partnering with pharmaceutical companies and other third parties; (viii) our expectations regarding revenue from sales of CELSignia tests and revenue from milestone or other payment sources; (ix) our plans with respect to research and development and related expenses for the foreseeable future; (x) our expectations regarding business development activities, including companion diagnostic related activities with pharmaceutical companies, expanding our sales and marketing functions and the costs associated with such activities; (xi) our expectations with respect to the CELSignia tests and the analytical capabilities of such tests; (xii) our beliefs regarding the ability of our cash on hand to fund our research and development expenses, capital expenditures, working capital, sales and marketing expenses, and general corporate expenses, as well as the increased costs associated with being a public company; and (xiii) our expectations regarding the impact that the COVID-19 pandemic and related economic effects will have on our business and results of operations.

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In some cases, you can identify forward-looking statements by the following words: “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “ongoing,” “plan,” “potential,” “predict,” “project,” “should,” “will,” “would,” or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. Forward-looking statements are only predictions and are not guarantees of performance. These statements are based on our management’s beliefs and assumptions, which in turn are based on their interpretation of currently available information.

These statements involve known and unknown risks, uncertainties and other factors that may cause our results or our industry’s actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Certain risks, uncertainties and other factors include, but are not limited to, our limited operating history; the unknown impact of the COVID-19 pandemic on our business; our initial success being heavily dependent on the success of our CELSignia HER2 Pathway Activity Test; our inability to develop and commercialize gedatolisib; our inability to determine whether our CELSignia tests are currently commercially viable; challenges we may face in developing and maintaining relationships with pharmaceutical company partners; the complexity and timeline for development of CELSignia tests and gedatolisib; the uncertainty and costs associated with clinical trials; the uncertainty regarding market acceptance by physicians, patients, third-party payors and others in the medical community, and with the size of market opportunities available to us; the pricing of molecular and other diagnostic products and services that compete with us; uncertainty with insurance coverage and reimbursement for our CELSignia tests; difficulties we may face in managing growth, such as hiring and retaining a qualified sales force and attracting and retaining key personnel; changes in government regulations; and obtaining and maintaining intellectual property protection for our technology and time and expense associated with defending third-party claims of intellectual property infringement, investigations or litigation threatened or initiated against us. These and additional risks, uncertainties and other factors are described more fully in our Annual Report on Form 10-K for the year ended December 31, 2020 and in Exhibit 99.4 to our Current Report on Form 8-K, filed with the SEC on April 8, 2021 and elsewhere in this Quarterly Report. Copies of filings made with the SEC are available through the SEC’s electronic data gathering analysis and retrieval system (EDGAR) at www.sec.gov.

You should read the cautionary statements made in this Quarterly Report as being applicable to all related forward-looking statements wherever they appear in this Quarterly Report. We cannot assure you that the forward-looking statements in this Quarterly Report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. You should read this Quarterly Report completely. Other than as required by law, we undertake no obligation to update these forward-looking statements, even though our situation may change in the future.

ITEM 3. Quantitative and Qualitative Disclosures about Market Risk

As a smaller reporting company, we are not required to provide disclosure pursuant to this item.

ITEM 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our Chief Executive Officer and Chief Financial Officer, referred to collectively herein as the Certifying Officers, are responsible for establishing and maintaining our disclosure controls and procedures. The Certifying Officers have reviewed and evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) promulgated under the Securities Exchange Act of 1934, as amended (the “Exchange Act”)) as of June 30, 2021. Based on that review and evaluation, the Certifying Officers have concluded that, as of the end of the period covered by this Quarterly Report, our disclosure controls and procedures, as designed and implemented, are effective and provide reasonable assurance that information required to be disclosed by us in the periodic and current reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the periods specified by the SEC’s rules and forms.

Changes in Internal Control Over Financial Reporting.

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the three months ended June 30, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II. — OTHER INFORMATION

ITEM 1. Legal Proceedings

From time to time we may be involved in disputes or litigation relating to claims arising out of our operations. We are not currently a party to any legal proceedings that could reasonably be expected to have a material adverse effect on our business, financial condition and results of operations.

ITEM 1A. Risk Factors

As a smaller reporting company, we are not required to provide disclosure pursuant to this item. However, in addition to other information set forth in this Quarterly Report, including the important information in the section entitled “Private Securities Litigation Reform Act,” you should carefully consider the “Risk Factors” discussed in our Annual Report on Form 10-K for the year ended December 31, 2020 and in Exhibit 99.4 to our Current Report on Form 8-K, filed with the SEC on April 8, 2021 for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in this Quarterly Report. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial might materially adversely affect our actual business, financial condition and/or operating results. You should also consider the following risk factor:

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

Use of Proceeds from Initial Public Offering of Common Stock

On September 22, 2017, we completed our initial public offering of 2,760,000 shares of our common stock at a price to the public of \$9.50 per share. The total number of shares of common stock sold in the offering includes the exercise of an overallotment we granted to Craig-Hallum Capital Group LLC, the sole managing underwriter of the offering, to purchase 360,000 shares of common stock. The shares of common stock were registered for sale pursuant to Registration Statements on Form S-1 (Registration Nos. 333-220128 and 333-220527), filed with the SEC and declared effective on September 19, 2017 (the “Effective Date”). The aggregate offering price for the registered shares of common stock was approximately \$26.2 million. The offering commenced on September 20, 2017 and did not terminate before all of the shares of common stock that were registered were sold.

The aggregate offering price for the shares of common stock sold in the offering was approximately \$26.2 million. We received net proceeds of approximately \$23.3 million from the offering, after deducting underwriting discounts and commissions of approximately \$1.8 million and offering expenses of approximately \$1.1 million. No payments for the foregoing expenses were made by us to any of our officers, directors or persons owning ten percent or more of our common stock, or to the associates of any of the foregoing, or to its affiliates, other than payments in the ordinary course of business to our officers for salaries and bonuses.

There has been no material change in the planned use of proceeds as described in our Prospectus filed with the SEC on September 20, 2017. From the Effective Date through June 30, 2021, we have used approximately \$17.5 million in furtherance of our planned use of proceeds, which includes funding additional research and development for discovery of new cancer sub-types and development and validation of new CELsignia tests; clinical trials to support clinical claims; development of operational processes and capital expenditures; and working capital and other general corporate purposes.

Recent Unregistered Sales of Equity Securities

None

ITEM 3. Defaults Upon Senior Securities

None.

ITEM 4. Mine Safety Disclosures

Not applicable.

ITEM 5. Other Information

None.

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ITEM 6. Exhibits

EXHIBIT INDEX

Exhibit No.	Description
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3.1	Certificate of Incorporation filed September 15, 2017, as amended by the Certificate of Amendment of Certificate of Incorporation, filed May 11, 2018, incorporated by reference from Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 9, 2018.
3.2	Bylaws, incorporated by reference from Exhibit 3.2 to the Company's Quarterly Report on Form 10-Q filed with the SEC on November 13, 2017.
4.1	Specimen Certificate representing shares of common stock of Celcuity Inc., incorporated by reference from Exhibit 4.1 to the Company's Registration Statement on Form S-1/A filed September 12, 2017.
4.2	Form of Warrant, incorporated by reference from Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the SEC on April 8, 2021.
4.3	Equity Grant Agreement, dated April 8, 2021, between the Company and Pfizer, Inc., incorporated by reference from Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on April 8, 2021.
10.1	Underwriting Agreement, dated June 28, 2021, between the Company, Jefferies LLC and Cowen and Company, LLC, incorporated by reference from Exhibit 1.1 to the Company's Current Report on Form 8-K filed with the SEC on June 30, 2021.
10.2*	Loan and Security Agreement, dated as of April 8, 2021, by and between the Company and Innovatus Life Sciences Lending Fund I, LP.
10.3*+	License Agreement, dated April 8, 2021, by and between the Company and Pfizer, Inc.

10.4*	Second Amendment to Lease, dated July 19, 2021, by and between the Company and West Glen Development I, LLC.
10.5*+	Amendment to License Agreement, dated May 6, 2021, by and between the Company and Pfizer, Inc.
31.1*	Certification of Chairman and Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Chairman and Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101*	Financial statements from the Quarterly Report on Form 10-Q of the Company for the quarter ended June 30, 2021, formatted in Inline XBRL: (i) the Condensed Balance Sheets, (ii) the Condensed Statements of Operations, (iii) the Condensed Statements of Changes in Stockholders' Equity, (iv) the Condensed Statements of Cash Flows, and (v) the Notes to Condensed Financial Statements.
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

- * Filed herewith.
** Furnished herewith.
+ Certain portions have been omitted from this exhibit.

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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.

Dated: August 11, 2021

CELCUITY INC.

By /s/ Brian F. Sullivan
Brian F. Sullivan
Chairman and Chief Executive Officer
(Principal Executive Officer)

By /s/ Vicky Hahne
Vicky Hahne
Chief Financial Officer
(Principal Financial and Accounting Officer)

LOAN AND SECURITY AGREEMENT

THIS LOAN AND SECURITY AGREEMENT (as the same may be amended, restated, modified, or supplemented from time to time, this “**Agreement**”) dated as of April 8, 2021 (the “**Effective Date**”) among INNOVATUS LIFE SCIENCES LENDING FUND I, LP, a Delaware limited partnership, as collateral agent (in such capacity, together with its successors and assigns in such capacity, “**Collateral Agent**”), and the Lenders listed on Schedule 1.1 hereof or otherwise a party hereto from time to time including INNOVATUS LIFE SCIENCES LENDING FUND I, LP in its capacity as a Lender, and CELCUITY, INC., a Delaware corporation (“**Borrower**”), provides the terms on which the Lenders shall lend to Borrower and Borrower shall repay the Lenders. The parties agree as follows:

1. DEFINITIONS, ACCOUNTING AND OTHER TERMS

1.1 Capitalized terms used herein shall have the meanings set forth in Section 13 to the extent defined therein. All other capitalized terms used but not defined herein shall have the meaning given to such terms in the Code. Any accounting term used but not defined herein shall be construed in accordance with GAAP and all calculations shall be made in accordance with GAAP. The term “financial statements” shall include the accompanying notes and schedules. Any section, subsection, schedule or exhibit references are to this Agreement unless otherwise specified.

2. LOANS AND TERMS OF PAYMENT

2.1 Promise to Pay. Borrower hereby unconditionally promises to pay each Lender the outstanding principal amount of the Term Loan advanced to Borrower by such Lender and accrued and unpaid interest thereon and any other amounts due hereunder as and when due in accordance with this Agreement.

2.2 Term Loans.(a) Availability.

(i) Subject to the terms and conditions of this Agreement, the Lenders agree, severally and not jointly, to make a term loan to Borrower on the effective date in an aggregate principal amount of up to Fifteen Million Dollars (\$15,000,000.00) according to each Lender’s Term Loan Commitment as set forth on Schedule 1.1 hereto (the “**Term A Loan**”). After repayment, the Term A Loan may not be re-borrowed.

(ii) Subject to the terms and conditions of this Agreement, the Lenders agree, severally and not jointly, to make a term loan to Borrower during the Term B Draw Period in an aggregate principal amount of up to Five Million Dollars (\$5,000,000.00) according to each Lender’s Term Loan Commitment as set forth on Schedule 1.1 hereto (the “**Term B Loan**”). After repayment, the Term B Loan may not be re-borrowed.

(iii) Subject to the terms and conditions of this Agreement, the Lenders agree, severally and not jointly, to make a term loan to Borrower during the Term C Draw Period in an aggregate principal amount of up to Five Million Dollars (\$5,000,000.00) according to each Lender’s Term Loan Commitment as set forth on Schedule 1.1 hereto (the “**Term C Loan**,” each Term A Loan, Term B Loan and Term C Loan is referred to singly as a “**Term Loan**” and the Term A Loan, Term B Loan and the Term C Loan are referred to collectively as the “**Term Loans**”). After repayment, the Term C Loan may not be re-borrowed.

[Signature Page to Loan and Security Agreement]

(b) Repayment. Borrower shall make monthly payments of interest only commencing on the first (1st) Payment Date following the Funding Date of any Term Loan, and continuing on the Payment Date of each successive month thereafter through and including the Payment Date immediately preceding the Amortization Date. Borrower agrees to pay, on the Funding Date of each Term Loan, any initial partial monthly interest payment otherwise due for the period between the Funding Date of such Term Loan and the first Payment Date after such Funding Date. Commencing on the Amortization Date, and continuing on the Payment Date of each month thereafter, shall make equal monthly payments of principal, together with applicable interest, in arrears, to each Lender, as calculated by

Collateral Agent (which calculations shall be deemed correct absent manifest error) based upon: (1) the amount of such Lender's Term Loan, (2) the effective rate of interest, as determined in Section 2.3(a), and (3) a repayment schedule equal to (i) in the case of the I/O Extension Event not occurring, twenty-four (24) months or (ii) in the case of I/O Extension Event occurring, twelve (12) months. All unpaid principal and accrued and unpaid interest with respect to the Term Loan is due and payable in full on the Maturity Date. The Term Loan may only be prepaid in accordance with Sections 2.2(c) and 2.2(d).

(c) Mandatory Prepayments. If an event described in Section 7.2(c)(ii) occurs or the Term Loan is accelerated following the occurrence of an Event of Default, Borrower shall immediately pay to Lenders, payable to each Lender in accordance with its respective Pro Rata Share, an amount equal to the sum of: (i) all outstanding principal of the Term Loan plus accrued and unpaid interest thereon through the prepayment date, (ii) the Final Fee, (iii) the Prepayment Fee, plus (iv) all other Obligations that are due and payable, including, without limitation, Lenders' Expenses and interest at the Default Rate with respect to any past due amounts. Notwithstanding (but without duplication with) the foregoing, on the Maturity Date, if the Final Fee had not previously been paid in full in connection with the prepayment of the Term Loan in full, Borrower shall pay to each Lender in accordance with its respective Pro Rata Share, the Final Fee in respect of the Term Loan.

(d) Permitted Prepayment of Term Loan. After the date that is the first anniversary of the Effective Date of the Term Loan, the Borrower shall have the option to prepay all, but not less than all, of the Term Loan advanced by the Lenders under this Agreement, provided Borrower (i) provides written notice to Collateral Agent of its election to prepay the Term Loan at least seven (7) Business Days prior to such prepayment, and (ii) pays to Collateral Agent for the benefit of each Lenders on the date of such prepayment, payable to each Lender in accordance with its respective Pro Rata Share, an amount equal to the sum of (A) all outstanding principal of the Term Loan plus accrued and unpaid interest thereon through the prepayment date, (B) the Final Fee, (C) the Prepayment Fee, plus (D) all other outstanding Obligations that are due and payable, including, without limitation, Lenders' Expenses and interest at the Default Rate with respect to any past due amounts.

Notwithstanding anything herein to the contrary, after the first anniversary of the Effective Date, Borrower shall also have the option to prepay part of Term Loans advanced by the Lenders under this Agreement, provided Borrower (i) provides written notice to Collateral Agent of its election to prepay the Term Loans at least seven (7) Business Days prior to such prepayment, (ii) prepays such part of the Term Loans in a principal amount of Five Million Dollars (\$5,000,000.00) or a whole multiple of One Million Dollars (\$1,000,000.00) in excess thereof, and (iii) pays to the Lenders on the date of such prepayment, payable to each Lender in accordance with its respective Pro Rata Share, an amount equal to the sum of (A) the portion of outstanding principal of such Term Loans plus all accrued and unpaid interest thereon through the prepayment date, (B) the applicable Final Fee, and (C) all other Obligations that are then due and payable, including Lenders' Expenses and interest at the Default Rate with respect to any past due amounts, and (D) the applicable Prepayment Fee with respect to the portion of such Term Loans being prepaid. For the purposes of clarity, any partial prepayment shall be applied pro-rata to all outstanding amounts under each Term Loan, and shall be applied pro-rata within each Term Loan tranche to reduce amortization payments under Section 2.2(b) on a pro-rata basis.

2.3 Payment of Interest on the Term Loan.

(a) Interest Rate Subject to Section 2.3(b), the principal amount outstanding under the Term Loan shall accrue interest at a floating per annum rate equal to the Basic Rate, determined by Collateral Agent on the Funding Date of the Term Loan and monthly thereafter, which interest shall be payable monthly in arrears in accordance with Sections 2.2(b) and 2.3(e); provided that at the election of Borrower (which shall be considered elected on the Funding Date of the applicable Term Loan) with no less than five (5) Business Days' written notice to Collateral Agent prior to the Funding Date, 2.70% of the Basic Rate may be payable in-kind by adding an amount equal to such 2.70% of the outstanding principal amount to the then outstanding principal balance on a monthly basis until the third anniversary of the Effective Date so as to increase the outstanding principal balance of the Term Loan on each Payment Date and which amount shall be payable when the principal amount of the applicable Term Loan is payable in accordance with Sections 2.2(b) and 2.3(e) and on which principal amount interest shall be owed pursuant to Section 2.3(a).

Interest shall accrue on each Term Loan commencing on, and including, the Funding Date of such Term Loan, and shall accrue on the principal amount outstanding under such Term Loan through and including the day on which such Term Loan is paid in full.

(b) Default Rate. Immediately upon the occurrence and during the continuance of an Event of Default, Obligations shall accrue interest at a floating per annum rate equal to the rate that is otherwise applicable thereto plus five percentage points (5.00%) (the "**Default Rate**"). Payment or acceptance of the increased interest rate provided in this Section 2.3(b) is not a permitted alternative

to timely payment and shall not constitute a waiver of any Event of Default or otherwise prejudice or limit any rights or remedies of Collateral Agent.

(c) 365 Day Year. Interest shall be computed on the basis of a three hundred sixty-five (365) day year and the actual number of days elapsed.

(d) Debit of Accounts. Collateral Agent and each Lender may debit (or ACH) any deposit accounts maintained by Borrower or any of its Subsidiaries for principal and interest payments or any other amounts Borrower owes the Lenders under the Loan Documents when due. Any such debits (or ACH activity) shall not constitute a set off.

(e) Payments. Except as otherwise expressly provided herein, all payments by Borrower under the Loan Documents shall be made to the respective Lender to which such payments are owed, at such Lender's office in immediately available funds on the date specified herein. Unless otherwise provided, interest is payable monthly on the Payment Date of each month. Payments of principal and/or interest received after 12:00 noon Eastern time are considered received at the opening of business on the next Business Day. When a payment is due on a day that is not a Business Day, the payment is due the next Business Day and additional fees or interest, as applicable, shall continue to accrue until paid. All payments to be made by Borrower hereunder or under any other Loan Document, including payments of principal and interest, and all fees, expenses, indemnities and reimbursements, shall be made without set off, recoupment or counterclaim, in lawful money of the United States and in immediately available funds.

(f) Changes in Prime Rate. In the event the Prime Rate is changed from time to time hereafter and because of any such change the Basic Rate changes (in accordance with its definition), the Basic Rate shall be increased or decreased, effective as of the day of such change in the Prime Rate.

2.4 Fees. Borrower shall pay to Collateral Agent:

(a) Facility Fee. The Facility Fee, which shall be due on the Funding Date of each Term Loan, to be shared among the Lenders in accordance with their respective Pro Rata Shares;

(b) Final Fee. The Final Fee, when due hereunder, to be shared among the Lenders in accordance with their respective Pro Rata Shares;

(c) Prepayment Fee. The Prepayment Fee, when due hereunder, to be shared among the Lenders in accordance with their respective Pro Rata Shares; and

(d) Lenders' Expenses. All Lenders' Expenses (including reasonable attorneys' fees and expenses for due diligence, investigation, documentation and negotiation of this Agreement) incurred through and after the Effective Date, when due; provided that no more than \$150,000 of Lenders' Expenses incurred through the Effective Date shall be payable by Borrower.

2.5 Withholding. Payments received by the Collateral Agent or the Lenders from Borrower hereunder will be made free and clear of and without deduction for any and all present or future taxes, levies, imposts, duties, deductions, withholdings, assessments, fees or other charges imposed by any governmental authority (including any interest, additions to tax or penalties applicable thereto). Specifically, however, if at any time any Governmental Authority, applicable law, regulation or international agreement requires Borrower to make any withholding or deduction from any such payment or other sum payable hereunder to the Lenders (other than any withholding or deduction attributable to taxes imposed on or measured by net income (however denominated), franchise taxes, and branch profits taxes, in each case, imposed as a result of such Lender being organized under the laws of, or having its principal office or its applicable lending office located in, the jurisdiction imposing such tax (or any political subdivision thereof)), Borrower hereby covenants and agrees that the amount due from Borrower with respect to such payment or other sum payable hereunder will be increased to the extent necessary to ensure that, after the making of such required withholding or deduction, each Lender receives a net sum equal to the sum which it would have received had no withholding or deduction been required and Borrower shall pay the full amount withheld or deducted to the relevant Governmental Authority; provided, however, that Borrower shall not be required to make such increased payment to a Lender who is not a U.S. Person or who has not provided a duly executed original IRS Form W-9 or other similar document certifying that such Lender is exempt from U.S. federal backup withholding tax. Borrower will, upon request, furnish the Lenders with proof reasonably satisfactory to the Lenders indicating that Borrower has made such withholding payment; provided, however, that Borrower need not make any withholding payment if the amount or validity of such withholding payment is contested in good faith by appropriate and timely

proceedings and as to which payment in full is bonded or reserved against by Borrower. The agreements and obligations of Borrower contained in this Section 2.5 shall survive the termination of this Agreement.

2.6 Secured Promissory Notes. The Term Loans shall be evidenced by a Secured Promissory Note or Notes in the form attached as Exhibit D hereto (each a “**Secured Promissory Note**”), and shall be repayable as set forth in this Agreement. Borrower irrevocably authorizes each Lender to make or cause to be made, on or about the Funding Date of any Term Loan or at the time of receipt of any payment of principal on such Lender’s Secured Promissory Note, an appropriate notation on such Lender’s Secured Promissory Note Record reflecting the making of such Term Loan or (as the case may be) the receipt of such payment. The outstanding amount of each Term Loan set forth on such Lender’s Secured Promissory Note Record shall be prima facie evidence of the principal amount thereof owing and unpaid to such Lender, but the failure to record, or any error in so recording, any such amount on such Lender’s Secured Promissory Note Record shall not limit or otherwise affect the obligations of Borrower under any Secured Promissory Note or any other Loan Document to make payments of principal of or interest on any Secured Promissory Note when due. Upon receipt of an affidavit of an officer of a Lender as to the loss, theft, destruction, or mutilation of its Secured Promissory Note, Borrower shall issue, in lieu thereof, a replacement Secured Promissory Note in the same principal amount thereof and of like tenor.

2.7 Conversion To Equity. Lenders shall have the right at their election, but not the obligation, after June 1, 2021 (provided that if an Acquisition occurs (as defined in the Warrant) the Lenders may exercise the rights contained in this Section 2.7 at any time) until the third anniversary of the Effective Date, to convert up to twenty percent (20.00%) of the outstanding principal amount of all of the Term Loans made hereunder into shares of Common Stock of Borrower at a price per share of \$14.40, which price shall be subject to appropriate adjustment for any stock split, stock dividend, combination, or other recapitalization or reclassification effected after the date hereof). Such shares shall be referred to herein as “**Borrower Equity**”.

To exercise their rights under this Section 2.7, the applicable Lender(s) shall notify Borrower in writing of the then outstanding principal amount of the Term Loans that is to be converted into Borrower Equity. Borrower shall no later than seven (7) days after the receipt of such notice issue the applicable number of shares of its Common Stock to the applicable Lender(s). Upon issuance of Borrower Equity in accordance with the provisions of this Section 2.7, the principal amount of Term Loans so converted shall deemed to have been prepaid for the purposes of this Agreement, provided, however, no Prepayment Fee or Final Fee shall be due with respect to such deemed prepayment. The applicable Lenders shall also in connection with the issuance of Borrower’s equity securities pursuant to this Section 2.7, enter into such agreements as reasonably requested by Borrower with customary terms and provisions for such transactions.

3. CONDITIONS OF LOANS

3.1 Conditions Precedent to Initial Term Loan. Each Lender’s obligation to make the Term Loan A is subject to the condition precedent that Collateral Agent and each Lender shall consent to or shall have received, in form and substance satisfactory to Collateral Agent and each Lender, such documents, and completion of such other matters, as Collateral Agent and each Lender may reasonably deem necessary or appropriate, including, without limitation:

- (a) original Loan Documents, each duly executed by Borrower and each Subsidiary, as applicable;
- (b) confirmation that Borrower’s market capitalization based on the closing price of shares of its Common Stock on NASDAQ on the last Business Day prior to the Effective Date is at least One Hundred Million Dollars (\$100,000,000.00);
- (c) a completed Perfection Certificate for Borrower and each of its Subsidiaries;
- (d) Reserved.
- (e) the Operating Documents and good standing certificates of Borrower and its Subsidiaries certified by the Secretary of State (or equivalent agency) of Borrower’s and such Subsidiaries’ jurisdiction of organization or formation and each jurisdiction in which Borrower and each Subsidiary is qualified to conduct business, each as of a date no earlier than thirty (30) days prior to the Effective Date;
- (f) a copy of resolutions of the governing body for Borrower evidencing approval of the Term Loan and other transactions evidenced by the Loan Documents;

(g) duly executed original officer's certificates for Borrower and each Subsidiary that is a party to the Loan Documents certifying as to (i) the incumbency of each Responsible Officer executing each Loan Document and (ii) the documents delivered pursuant to Section 3.1(d) and 3.1(e), in a form acceptable to Collateral Agent and the Lenders;

(h) certified copies, dated as of date no earlier than thirty (30) days prior to the Effective Date, of financing statement searches, as Collateral Agent shall request, accompanied by written evidence (including any UCC termination statements) that the Liens indicated in any such financing statements either constitute Permitted Liens or have been or, in connection with the initial Term Loan, will be terminated or released;

(i) a duly executed legal opinion of counsel to Borrower dated as of the Effective Date;

(j) evidence satisfactory to Collateral Agent and the Lenders that the insurance policies required by Section 6.5 hereof are in full force and effect, together with appropriate evidence showing loss payable and/or additional insured clauses or endorsements in favor of Collateral Agent, for the ratable benefit of the Lenders;

(k) a copy of any applicable Investors Rights Agreement and any amendments thereto;

(l) payment of the Facility Fee and Lenders' Expenses then due as specified in Section 2.4 hereof;

(m) a landlord's consent executed in favor of Collateral Agent in respect of all of Borrower's and each Subsidiaries' leased locations; and

(n) a bailee waiver executed in favor of Collateral Agent in respect of each third party bailee where Borrower or any Subsidiary maintains Collateral having a book value in excess of Three Hundred Fifty Thousand Dollars (\$300,000.00).

3.2 Conditions Precedent to all Term Loans. The obligation of each Lender to extend each Term Loan, including the Term A Loan, is subject to the following conditions precedent:

(a) receipt by Collateral Agent of (i) an executed Loan Payment Request Form in the form of EXHIBIT B-1 attached hereto and (ii) an executed Disbursement Letter in the form of EXHIBIT B-2 attached hereto;

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(b) the representations and warranties in Section 5 hereof shall be true, accurate and complete in all material respects on the date of each Loan Payment Request Form and the date of each Disbursement Letter and the Funding Date of each Term Loan; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date, and no Event of Default shall have occurred and be continuing or result from the funding of such Term Loan;

(c) in such Lender's reasonable discretion, there has not been any Material Adverse Change;

(d) no Event of Default or an event that with the passage of time could result in an Event of Default, shall exist;

(e) to the extent not delivered at the Effective Date, duly executed original Secured Promissory Notes and Warrants, in number, form and content acceptable to each Lender, and in favor of each Lender according to its Commitment Percentage, with respect to each Credit Extension made by such Lender after the Effective Date;

(f) if such Term Loan is the Term B Loan, all of the Term B Milestones must have been met;

(g) if such Term Loan is the Term C Loan, the Term C Milestone must have been met; and

(h) payment of the fees and Lenders' Expenses then due as specified in Section 2.5 hereof.

3.3 Covenant to Deliver. Borrower agrees to deliver to Collateral Agent and the Lenders each item required to be delivered to Collateral Agent under this Agreement as a condition precedent to any Term Loan. Borrower expressly agrees that any Term Loan made

prior to the receipt by Collateral Agent or any Lender of any such item shall not constitute a waiver by Collateral Agent or any Lender of Borrower's obligation to deliver such item, and any such Term Loan in the absence of a required item shall be made in each Lender's sole discretion.

3.4 Procedures for Borrowing. Subject to the prior satisfaction of all other applicable conditions to the making of any Term Loan set forth in this Agreement, to obtain the Term Loan (other than the Term Loan funded on the Effective Date), Borrower shall notify the Lenders (which notice shall be irrevocable) by electronic mail, facsimile, or telephone by 12:00 noon New York City time ten (10) Business Days (or such shorter period as acceptable to the Lenders in their sole discretion) prior to the date the Term Loan is to be made. Together with any such electronic, facsimile or telephonic notification, Borrower shall deliver to Collateral Agent by electronic mail or facsimile a completed Disbursement Letter and Loan Payment Request Form executed by a Responsible Officer or his or her designee. The Collateral Agent may rely on any telephone notice given by a person whom Collateral Agent reasonably believes is a Responsible Officer or designee.

4. CREATION OF SECURITY INTEREST

4.1 Grant of Security Interest. Borrower hereby grants Collateral Agent, for the ratable benefit of the Lenders, to secure the payment and performance in full of all of the Obligations, a continuing security interest in, and pledges to Collateral Agent, for the ratable benefit of the Lenders, the Collateral, wherever located, whether now owned or hereafter acquired or arising, and all proceeds and products thereof. If Borrower shall acquire a commercial tort claim (as defined in the Code) having a value in excess of \$100,000 (other than unasserted commercial tort claims), Borrower shall grant to Collateral Agent, for the ratable benefit of the Lenders, a security interest therein and in the proceeds thereof, all upon the terms of this Agreement, with such writing to be in form and substance reasonably satisfactory to Collateral Agent.

If this Agreement is terminated, Collateral Agent's Lien in the Collateral shall continue until the Obligations (other than inchoate indemnity obligations) are repaid in full in cash. Upon payment in full in cash of the Obligations (other than inchoate indemnity obligations) and at such time as the Lenders' obligation to extend the Term Loan has terminated, Collateral Agent shall, at the sole cost and expense of Borrower, release its Liens in the Collateral and all rights therein shall revert to Borrower, and Collateral Agent shall, at the sole cost and expense of Borrower, execute and deliver (and authorize Borrower and any of its designees to file) such terminations, releases and other documentation as necessary and requested by Borrower to evidence such release.

4.2 Authorization to File Financing Statements. Borrower hereby authorizes Collateral Agent to file financing statements or take any other action required to perfect Collateral Agent's security interests in the Collateral, without notice to Borrower, with all appropriate jurisdictions to perfect or protect Collateral Agent's interest or rights under the Loan Documents.

4.3 Pledge of Collateral. Borrower hereby pledges, assigns and grants to Collateral Agent, for the ratable benefit of the Lenders, a security interest in all the Shares, together with all proceeds and substitutions thereof, all cash, stock and other moneys and property paid thereon, all rights to subscribe for securities declared or granted in connection therewith, and all other cash and noncash proceeds of the foregoing, as security for the performance of the Obligations. On the Effective Date, or, to the extent not certificated as of the Effective Date, within ten (10) days of the certification of any such Shares, the certificate or certificates for such Shares will be delivered to Collateral Agent, accompanied by an instrument of assignment duly executed in blank by Borrower. To the extent required by the terms and conditions governing such Shares, Borrower shall cause the books of each entity whose Shares are part of the Collateral and any transfer agent to reflect the pledge of the Shares. Upon the occurrence and during the continuance of an Event of Default hereunder, Collateral Agent may effect the transfer of any securities included in the Collateral (including but not limited to the Shares) into the name of Collateral Agent and cause new (as applicable) certificates representing such securities to be issued in the name of Collateral Agent or its transferee. Borrower will execute and deliver such documents, and take or cause to be taken such actions, as Collateral Agent may reasonably request to perfect or continue the perfection of Collateral Agent's security interest in the Shares. Unless an Event of Default shall have occurred and be continuing, Borrower shall be entitled to exercise any voting rights with respect to the Shares and to give consents, waivers and ratifications in respect thereof, provided that no vote shall be cast or consent, waiver or ratification given or action taken which would be inconsistent with any of the terms of this Agreement or which would constitute or create any violation of any of such terms. All such rights to vote and give consents, waivers and ratifications shall terminate upon the occurrence and continuance of an Event of Default.

5. REPRESENTATIONS AND WARRANTIES

Borrower represents and warrants to Collateral Agent and the Lenders as follows:

5.1 Due Organization, Authorization: Power and Authority. Borrower and each of its Subsidiaries is duly existing and in good standing as a Registered Organization in its jurisdictions of organization or formation and Borrower and each of its Subsidiaries is qualified and licensed to do business and is in good standing in any jurisdiction in which the conduct of its businesses or its ownership of property requires that it be qualified except where the failure to do so could not reasonably be expected to have a Material Adverse Change. In connection with this Agreement, Borrower and each of its Subsidiaries has delivered to Collateral Agent a completed perfection certificate and any updates or supplements thereto on or before the Effective Date (each a “**Perfection Certificate**” and collectively, the “**Perfection Certificates**”). Borrower represents and warrants that all the information set forth on the Perfection Certificates pertaining to Borrower and each of its Subsidiaries is accurate and complete in all material respects.

The execution, delivery and performance by Borrower and each of its Subsidiaries of the Loan Documents to which it is a party have been duly authorized, and do not (i) conflict with any of Borrower’s or such Subsidiaries’ organizational documents, including its respective Operating Documents, (ii) contravene, conflict with, constitute a default under or violate any material Requirement of Law applicable thereto, (iii) contravene, conflict or violate any applicable order, writ, judgment, injunction, decree, determination or award of any Governmental Authority by which Borrower or such Subsidiary, or any of their property or assets may be bound or affected, (iv) require any action by, filing, registration, or qualification with, or Governmental Approval from, any Governmental Authority (except such Governmental Approvals which have already been obtained and are in full force and effect) or are being obtained pursuant to Section 6.1(b), or (v) constitute an event of default under any material agreement by which Borrower or any of such Subsidiaries, or their respective properties, is bound. Neither Borrower nor any of its Subsidiaries is in default under any agreement to which it is a party or by which it or any of its assets is bound in which such default could reasonably be expected to have a Material Adverse Change.

5.2 Collateral.

(a) Borrower and each its Subsidiaries have good title to, have rights in, and the power to transfer each item of the Collateral upon which it purports to grant a Lien under the Loan Documents, free and clear of any and all Liens except Permitted Liens, and neither Borrower nor any of its Subsidiaries have any Deposit Accounts, Securities Accounts, Commodity Accounts or other investment accounts other than the Collateral Accounts or the other investment accounts, if any, described in the Perfection Certificates delivered to Collateral Agent in connection herewith with respect of which Borrower or such Subsidiary has given Collateral Agent notice and taken such actions as are necessary to give Collateral Agent a perfected security interest therein. To the Borrower’s Knowledge, the Accounts are bona fide, existing obligations of the Account Debtors.

(b) The security interest granted herein is and shall at all times continue to be a first priority perfected security interest in the Collateral, subject only to Permitted Liens that are permitted by the terms of this Agreement to have priority to Collateral Agent’s Lien.

(c) On the Effective Date, and except as disclosed on the Perfection Certificate (i) the Collateral is not in the possession of any third party bailee, and (ii) no such third party bailee possesses components of the Collateral with a book value in excess of Three Hundred Thousand Dollars (\$300,000.00).

(d) All Inventory and Equipment is in all material respects of good and marketable quality, free from material defects.

(e) Borrower and each of its Subsidiaries is the sole owner of the Intellectual Property each respectively purports to own, free and clear of all Liens other than Permitted Liens. Except as noted on the Perfection Certificates, neither Borrower nor any of its Subsidiaries is a party to, nor is bound by, any material license or other Material Agreement.

5.3 Litigation. Except as disclosed on the Perfection Certificate, there are no actions, suits, investigations, or proceedings pending or, to the Knowledge of the Responsible Officers, threatened in writing by or against Borrower or any of its Subsidiaries involving more than Two Hundred Fifty Thousand Dollars (\$250,000.00) or a claim for infringement of any intellectual property. Except as disclosed on the Perfection Certificate, there are no actions, suits, investigations or proceedings pending or, to the Knowledge of the Responsible Officers, threatened in writing by or against Borrower or any Subsidiaries involving challenges to the validity of the Intellectual Property.

5.4 No Material Adverse Change; Financial Statements. All consolidated financial statements for Borrower and its Subsidiaries, delivered to Collateral Agent fairly present, in conformity with GAAP, in all material respects the consolidated financial condition of Borrower and its Subsidiaries, and the consolidated results of operations of Borrower and its Subsidiaries. Since the date of the most recent financial statements submitted to any Lender, there has not been a Material Adverse Change.

5.5 Solvency. Borrower and each of its Subsidiaries, when taken as a whole, are Solvent.

5.6 Regulatory Compliance. Neither Borrower nor any of its Subsidiaries is an “investment company” or a company “controlled” by an “investment company” under the Investment Company Act of 1940, as amended. Neither Borrower nor any of its Subsidiaries is engaged as one of its important activities in extending credit for margin stock (under Regulations X, T and U of the Federal Reserve Board of Governors). Borrower and each of its Subsidiaries has complied in all material respects with the Federal Fair Labor Standards Act. Neither Borrower nor any of its Subsidiaries is a “holding company” or an “affiliate” of a “holding company” or a “subsidiary company” of a “holding company” as each term is defined and used in the Public Utility Holding Company Act of 2005. Neither Borrower nor any of its Subsidiaries has violated any laws, ordinances or rules, the violation of which could reasonably be expected to have a Material Adverse Change. Neither Borrower’s nor any of its Subsidiaries’ properties or assets has been used by Borrower or such Subsidiary or, to Borrower’s Knowledge, by previous Persons, in disposing, producing, storing, treating, or transporting any hazardous substance other than in material compliance with applicable laws. Borrower and each of its Subsidiaries has obtained all consents, approvals and authorizations of, made all declarations or filings with, and given all notices to, all Governmental Authorities that are necessary to continue their respective businesses as currently conducted.

None of Borrower, any of its Subsidiaries, or any of Borrower’s or its Subsidiaries’ Affiliates or any of their respective agents acting or benefiting in any capacity in connection with the transactions contemplated by this Agreement is (i) in violation of any Anti Terrorism Law, (ii) engaging in or conspiring to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding or attempts to violate, any of the prohibitions set forth in any Anti Terrorism Law, or (iii) is a Blocked Person. None of Borrower, any of its Subsidiaries, or to the Knowledge of Borrower and any of their Affiliates or agents, acting or benefiting in any capacity in connection with the transactions contemplated by this Agreement, (x) conducts any business or engages in making or receiving any contribution of funds, goods or services to or for the benefit of any Blocked Person, or (y) deals in, or otherwise engages in any transaction relating to, any property or interest in property blocked pursuant to Executive Order No. 13224, any similar executive order or other Anti Terrorism Law.

5.7 Investments. Neither Borrower nor any of its Subsidiaries owns any stock, shares, partnership interests or other equity securities except for Permitted Investments.

5.8 Tax Returns and Payments; Pension Contributions. Borrower and each of its Subsidiaries has timely filed all required tax returns and reports, and Borrower and each of its Subsidiaries, has timely paid all foreign, federal, state, and local taxes, assessments, tax deposits and tax contributions owed by Borrower and such Subsidiaries in an amount greater than Twenty-Five Thousand Dollars (\$25,000.00), in all jurisdictions in which Borrower or any such Subsidiary is subject to taxes, including the United States, unless such taxes are being contested in accordance with the next sentence. Borrower and each of its Subsidiaries, may defer payment of any contested taxes, provided that Borrower or such Subsidiary in good faith contests its obligation to pay the taxes by appropriate proceedings promptly and diligently instituted and conducted. Neither Borrower nor any of its Subsidiaries is aware of any claims or adjustments proposed for any of Borrower’s or such Subsidiaries’ prior tax years which could result in additional taxes becoming due and payable by Borrower or its Subsidiaries. Borrower and each of its Subsidiaries have paid all amounts necessary to fund all present pension, profit sharing and deferred compensation plans in accordance with their terms, and neither Borrower nor any of its Subsidiaries have, withdrawn from participation in, and have not permitted partial or complete termination of, or permitted the occurrence of any other event with respect to, any such plan which could reasonably be expected to result in any material liability of Borrower or its Subsidiaries, including any liability to the Pension Benefit Guaranty Corporation or its successors or any other Governmental Authority.

5.9 Use of Proceeds. Borrower shall use the proceeds of the Term Loans solely as working capital and to fund its general business requirements in accordance with the provisions of this Agreement, and not for personal, family, household or agricultural purposes.

5.10 Full Disclosure. No written representation, warranty or other statement of Borrower or any of its Subsidiaries in any certificate or written statement given to Collateral Agent or any Lender, as of the date such representation, warranty, or other statement was made, taken together with all such written certificates and written statements given to Collateral Agent or any Lender, contains

any untrue statement of a material fact or omits to state a material fact necessary to make the statements contained in the certificates or statements not misleading (it being recognized that projections and forecasts provided by Borrower in good faith and based upon reasonable assumptions are not viewed as facts and that actual results during the period or periods covered by such projections and forecasts may differ from the projected or forecasted results) and any failure to meet such projections shall not be deemed to be a breach of any representation herein; provided, however, such failure may constitute a breach of one or more specific covenants herein that are based on such projections).

5.11 Shares. Borrower has full power and authority to create a first lien on the Shares and no disability or contractual obligation exists that would prohibit Borrower from pledging the Shares pursuant to this Agreement. To Borrower's knowledge, there are no subscriptions, warrants, rights of first refusal or other restrictions on transfer relative to, or options exercisable with respect to the Shares. The Shares have been and will be duly authorized and validly issued, and are fully paid and non-assessable. To Borrower's knowledge, the Shares are not the subject of any present or threatened suit, action, arbitration, administrative or other proceeding, and Borrower knows of no reasonable grounds for the institution of any such proceedings.

6. AFFIRMATIVE COVENANTS

Borrower shall, and shall cause each of its Subsidiaries to, do all of the following:

6.1 Government Compliance.

(a) Maintain its and all its Subsidiaries' legal existence and good standing in their respective jurisdictions of organization and maintain qualification in each jurisdiction in which the failure to so qualify could reasonably be expected to have a Material Adverse Change. Comply with all laws, ordinances and regulations to which Borrower or any of its Subsidiaries is subject, the noncompliance with which could reasonably be expected to have a Material Adverse Change.

(b) Obtain and keep in full force and effect, all of the material Governmental Approvals necessary for the performance by Borrower and its Subsidiaries of their respective businesses and obligations under the Loan Documents and the grant of a security interest to Collateral Agent for the ratable benefit of the Lenders, in all of the Collateral.

6.2 Financial Statements, Reports, Certificates; Notices.

(a) Deliver to Collateral Agent and each Lender:

(i) as soon as available, but no later than thirty (30) days after the last day of each month of Borrower, a company prepared consolidated and consolidating balance sheet, income statement and cash flow statement covering the consolidated operations of Borrower and its Subsidiaries for such month certified by a Responsible Officer and in a form reasonably acceptable to Collateral Agent;

(ii) as soon as available, but no later than ninety (90) days after the last day of Borrower's fiscal year or within five (5) days of filing with the Securities and Exchange Commission, audited consolidated financial statements prepared under GAAP, consistently applied, together with an unqualified opinion on the financial statements from an independent certified public accounting firm acceptable to Collateral Agent in its reasonable discretion;

(iii) as soon as available after approval thereof by Borrower's board of directors, but no later than the earlier of ten (10) days after such approval and forty-five (45) days after the last day of Borrower's fiscal year, Borrower's annual (A) financial projections and (B) budget, in each case, for the entire current fiscal year as approved by Borrower's board of directors; provided that, any board approved revisions to such projections and/or budget approved by Borrower's board of directors shall be delivered to Collateral Agent and the Lenders no later than seven (7) days after such approval);

(iv) within five (5) days of delivery, copies of all material non-ministerial statements, reports and notices made available to Borrower's board of directors, security holders or holders of Subordinated Debt; provided, notwithstanding anything set forth in this Section 6.2(a)(iv), Borrower shall not be required to deliver any such statements, reports or notices (i) if Borrower determines in good faith and upon the advice of counsel that the receipt of such materials by Collateral Agent or the Lenders would jeopardize the attorney-client privilege between Borrower and its counsel, or any Subsidiary of Borrower and its counsel, (ii) if and to the extent

necessary, to protect highly confidential proprietary information of Borrower or any of its Subsidiaries or (iii) if information that is being disclosed in such materials relate to Borrower or Subsidiary's strategy, negotiating positions or similar matters relating to Collateral Agent or the Lenders;

(v) within five (5) days of filing, all reports on Form 10 K, 10 Q and 8 K filed with the Securities and Exchange Commission;

(vi) prompt notice of any amendments of or other changes to the Operating Documents of Borrower or any of its Subsidiaries, together with any copies reflecting such amendments or changes with respect thereto;

(vii) as soon as available, but no later than thirty (30) days after the last day of each month, copies of the month end account statements for each Collateral Account maintained by Borrower or its Subsidiaries, which statements may be provided to Collateral Agent and each Lender by Borrower or directly from the applicable institution(s);

(viii) prompt delivery of (and in any event within five (5) days after the same are sent or received) copies of all material correspondence, reports, documents and other filings with any Governmental Authority that could reasonably be expected to have a material adverse effect on any of the Governmental Approvals material to Borrower's business or otherwise could reasonably be expected to have a Material Adverse Change;

(ix) prompt notice of any event that (A) could reasonably be expected to materially and adversely affect the Borrower's Intellectual Property and (B) could reasonably be expected to result in a Material Adverse Change;

(x) written notice at least (10) days' prior to Borrower's creation of a New Subsidiary in accordance with the terms of Section 6.10;

(xi) written notice at least (15) days' prior to Borrower's (A) adding any new offices or business locations, including warehouses (unless such new offices or business locations contain less than Three Hundred Thousand Dollars (\$300,000.00) of book value in assets or property of Borrower or any of its Subsidiaries), (B) changing its jurisdiction of organization, (C) changing its organizational structure or type, (D) changing its legal name, or (E) changing any organizational number (if any) assigned by its jurisdiction of organization;

(xii) upon Borrower becoming aware of the existence of any Event of Default or event which, with the giving of notice or passage of time, or both, would constitute an Event of Default, prompt (and in any event within three (3) Business Days) written notice of such occurrence, which such notice shall include a reasonably detailed description of such Event of Default or event which, with the giving of notice or passage of time, or both, would constitute an Event of Default;

(xiii) immediate notice if Borrower or such Subsidiary has Knowledge that Borrower, or any Subsidiary or Affiliate of Borrower, is listed on the OFAC Lists or (a) is convicted on, (b) pleads *nolo contendere* to, (c) is indicted on, or (d) is arraigned and held over on charges involving money laundering or predicate crimes to money laundering;

(xiv) notice of any commercial tort claim in excess of \$100,000 (other than unasserted commercial tort claims) and of the general details thereof;

(xv) if Borrower or any of its Subsidiaries is not now a Registered Organization but later becomes one, written notice of such occurrence and information regarding such Person's organizational identification number within seven (7) Business Days of receiving such organizational identification number; and

(xvi) other information as reasonably requested by Collateral Agent or any Lender.

Notwithstanding the foregoing, documents required to be delivered pursuant to the terms hereof (to the extent any such documents are included in materials otherwise filed with the Securities and Exchange Commission) may be delivered electronically and if so delivered, shall be deemed to have been delivered on the date on which Borrower posts such documents, or provides a link thereto, on Borrower's website on the internet at Borrower's website address.

(b) Concurrently with the delivery of the financial statements specified in Section 6.2(a)(i) above but no later than thirty (30) days after the last day of each month, deliver to Collateral Agent and each Lender:

(i) a duly completed Compliance Certificate signed by a Responsible Officer;

(ii) if such month is the last month of the quarter, an updated Perfection Certificate to reflect any amendments, modifications and updates to certain information in the Perfection Certificate after the Effective Date to the extent such amendments, modifications and updates are permitted by one or more specific provisions in this Agreement; in each case, subject to the review and approval of Collateral Agent and each Lender;

(iii) copies of any material Governmental Approvals obtained by Borrower or any of its Subsidiaries;

(iv) written notice of the commencement of, and any material development in, the proceedings contemplated by Section 5.8 hereof;

(v) written notice of any litigation or governmental proceedings pending or threatened (in writing) against Borrower or any of its Subsidiaries, which could reasonably be expected to result in damages or costs to Borrower or any of its Subsidiaries of more than Two Hundred Fifty Thousand Dollars (\$250,000.00) not paid or covered by independent third party insurance; and

(vi) written notice of all returns, recoveries, disputes and claims regarding Inventory that involve more than Two Hundred Thousand Dollars (\$200,000.00) individually or in the aggregate in any calendar year.

(c) Keep proper, complete and true books of record and account in accordance with GAAP in all material respects. Borrower shall, and shall cause each of its Subsidiaries to, allow, at the sole cost of Borrower, Collateral Agent or any Lender, during regular business hours upon reasonable prior notice (provided that no notice shall be required when an Event of Default has occurred and is continuing), to visit and inspect any of its properties, to examine and make abstracts or copies from any of its books and records, and to conduct a collateral audit and analysis of its operations and the Collateral. Such audits shall be conducted no more often than once every year unless (and more frequently if) an Event of Default has occurred and is continuing provided that unless an Event of Default has occurred and is continuing. Notwithstanding the foregoing, upon request of any Lender, Borrower agrees to permit such Lender to communicate with Borrower's accounting firm with respect to the consolidated financial statements delivered pursuant to this Section 6.2, provided such communication shall be in the presence of an authorized representative of Borrower.

6.3 Inventory; Returns. Keep all Inventory in good and marketable condition, free from material defects. Returns and allowances between Borrower, or any of its Subsidiaries, and their respective Account Debtors shall follow Borrower's, or such Subsidiary's, customary practices as they exist at the Effective Date.

6.4 Taxes; Pensions. Timely file and require each of its Subsidiaries to timely file, all required tax returns and reports and timely pay, and require each of its Subsidiaries to timely pay, all foreign, federal, state, and local taxes, assessments, deposits and contributions owed by Borrower or its Subsidiaries, except as otherwise permitted pursuant to the terms of Section 5.8 hereof, and shall deliver to Collateral Agent and each Lender, on demand, appropriate certificates attesting to such payments, and pay all amounts necessary to fund all present pension, profit sharing and deferred compensation plans in accordance with the terms of such plans.

6.5 Insurance. Keep Borrower's and its Subsidiaries' business and the Collateral insured for risks and in amounts standard for companies in Borrower's and its Subsidiaries' industry and location and as Collateral Agent may reasonably request, including, but not limited to, D&O insurance reasonably satisfactory to Collateral Agent. Insurance policies shall be in a form, with companies, and in amounts that are reasonably satisfactory to Collateral Agent and Lenders. All property policies shall have a lender's loss payable endorsement showing Collateral Agent as lender loss payee and waive subrogation against Collateral Agent, and all liability policies shall show, or have endorsements showing, Collateral Agent, as additional insured. The Collateral Agent shall be named as lender loss

payee and/or additional insured with respect to any such insurance providing coverage in respect of any Collateral, and each provider of any such insurance shall agree, by endorsement upon the policy or policies issued by it or by independent instruments furnished to the Collateral Agent, that it will give the Collateral Agent thirty (30) days' prior written notice before any such policy or policies shall be materially altered or canceled (other than cancellation for non-payment of premiums, for which ten (10) days' prior written notice shall be required). At Collateral Agent's request, Borrower shall deliver certified copies of policies and evidence of all premium payments. Proceeds payable under any policy shall, at Collateral Agent's option, be payable to Collateral Agent, for the ratable benefit of the Lenders, on account of the Obligations. Notwithstanding the foregoing, (a) so long as no Event of Default has occurred and is continuing, Borrower shall have the right to apply the proceeds of any casualty policy within 180 days of receipt thereof up to Five Hundred Thousand Dollars (\$500,000.00) with respect to any loss, but not exceeding One Million Dollars (\$1,000,000.00), in the aggregate for all losses under all casualty policies in any one year, toward the replacement or repair of destroyed or damaged property; provided that any such replaced or repaired property (i) shall be of equal or like value as the replaced or repaired Collateral and (ii) shall be deemed Collateral in which Collateral Agent has been granted a first priority security interest, and (b) after the occurrence and during the continuance of an Event of Default, all proceeds payable under such casualty policy shall, at the option of Collateral Agent, be payable to Collateral Agent, for the ratable benefit of the Lenders, on account of the Obligations. If Borrower or any of its Subsidiaries fails to obtain insurance as required under this Section 6.5 or to pay any amount or furnish any required proof of payment to third persons, Collateral Agent and/or any Lender may make (but has no obligation to do so), at Borrower's expense, all or part of such payment or obtain such insurance policies required in this Section 6.5, and take any action under the policies Collateral Agent or such Lender deems prudent.

6.6 Operating Accounts.

(a) Borrower shall provide Collateral Agent ten (10) days' prior written notice before Borrower or any of its Subsidiaries establishes any Collateral Account. In addition, for each Collateral Account that Borrower or any of its Subsidiaries at any time maintains, Borrower or such Subsidiary shall cause the applicable bank or financial institution at or with which such Collateral Account is maintained to execute and deliver a Control Agreement or other appropriate instrument with respect to such Collateral Account to perfect Collateral Agent's Lien in such Collateral Account in accordance with the terms hereunder prior to the establishment of such Collateral Account, which Control Agreement may not be terminated without prior written consent of Collateral Agent. The provisions of the previous sentence shall not apply to deposit accounts exclusively used for payroll, payroll taxes and other employee wage and benefit payments to or for the benefit of Borrower's, or any of its Subsidiaries', employees and identified to Collateral Agent by Borrower as such in the Perfection Certificate.

(b) Neither Borrower nor any of its Subsidiaries shall maintain any Collateral Accounts except Collateral Accounts maintained in accordance with Section 6.6.

(c) Notwithstanding anything herein to the contrary:

(i) Borrower shall deliver no later than seven (7) days after the Effective Date, Borrower shall deliver fully executed Control Agreement(s) in favor of Collateral Agent, with respect to at least one bank account of Borrower (or if Borrower despite making commercially reasonable efforts is unable to deliver the such fully executed Control Agreement(s) seven (7) days after the Effective Date, then in any event no later than fifteen (15) days after the after the Effective Date Borrower shall deliver such fully executed Control Agreement(s));

(ii) On or before Borrower shall deliver no later than sixty (60) days after the Effective Date (or if Borrower despite making commercially reasonable efforts is unable to deliver the applicable fully executed Control Agreement(s) sixty (60) days after the Effective Date, then in any event no later than ninety (90) days after the after the Effective Date), Borrower shall deliver fully executed Control Agreement(s) in favor of Collateral Agent with respect to all Collateral Accounts of Borrower. Until such time as Borrower delivered fully executed Control Agreements with respect to all of its Collateral Accounts, Borrower shall at all times maintain a minimum cash balance of Fifteen Million Dollars (\$15,000,000.00) in such account(s) with respect to which Borrower has delivered fully executed Control Agreement(s) in accordance with Section 6.7(c)(i) after such Control Agreement(s) have been delivered.

6.7 Protection of Intellectual Property Rights. Borrower and each of its Subsidiaries shall: (a) protect, defend and maintain the validity and enforceability of its Intellectual Property that is material to its business; (b) promptly advise Collateral Agent in writing of a challenge to the validity, or material infringement by a third party of its Intellectual Property; and (c) not allow any Intellectual Property material to its business to be abandoned, forfeited or dedicated to the public without Collateral Agent's prior written consent.

6.8 Litigation Cooperation. Commencing on the Effective Date and continuing through the termination of this Agreement, make available to Collateral Agent and the Lenders, without expense to Collateral Agent or the Lenders, Borrower and each of Borrower's officers, employees and agents and Borrower's Books, to the extent that Collateral Agent or any Lender may reasonably deem them necessary to prosecute or defend any third party suit or proceeding instituted by or against Collateral Agent or any Lender with respect to any Collateral or relating to Borrower.

6.9 Landlord Waivers; Bailee Waivers. In the event that Borrower or any of its Subsidiaries, after the Effective Date, intends to add any new offices or business locations, including warehouses, or otherwise store any portion of the Collateral with, or deliver any portion of the Collateral to, a bailee, in each case pursuant to Section 7.2, then Borrower or such Subsidiary will first notify Collateral Agent and, in the event that the Collateral at any new location is valued in excess of Three Hundred Thousand Dollars (\$300,000.00) in the aggregate, at Collateral Agent's election, such bailee or landlord, as applicable, must execute and deliver a bailee waiver or landlord waiver, as applicable, in form and substance reasonably satisfactory to Collateral Agent prior to the addition of any new offices or business locations, or any such storage with or delivery to any such bailee, as the case may be.

6.10 Creation/Acquisition of Subsidiaries. In the event any Borrower or any Subsidiary of any Borrower creates or acquires any Subsidiary after the Effective Date, Borrower or such Subsidiary shall promptly notify Collateral Agent of such creation or acquisition, and Borrower or such Subsidiary shall take all actions reasonably requested by Collateral Agent to achieve any of the following with respect to such "New Subsidiary" (defined as a Subsidiary formed after the date hereof during the term of this Agreement): (i) to cause such New Subsidiary to become either a co-Borrower hereunder, if such New Subsidiary is organized under the laws of the United States, or a secured guarantor with respect to the Obligations; and (ii) to grant and pledge to Collateral Agent a perfected security interest in the Shares of such New Subsidiary.

6.11 Further Assurances. Execute any further instruments and take further action as Collateral Agent or any Lender reasonably requests to perfect or continue Collateral Agent's Lien in the Collateral or to effect the purposes of this Agreement, including without limitation, subject to the terms of Section 6.2(c) permitting Collateral Agent or any Lender to discuss Borrower's financial condition with Borrower's accountants.

6.12 Financial Covenant. Prior to the occurrence of the FDA Approval Event, during each fiscal quarter (or if applicable, part thereof) Borrower shall maintain in Collateral Accounts subject to Control Agreements in favor of Collateral Agent aggregate unrestricted cash balance of not less than the following aggregate amounts:

Volume weighted average market capitalization of Borrower during the immediately preceding quarter (\$ million):	Minimum aggregate unrestricted cash balance in Collateral Accounts (subject to Control Agreements in favor of Collateral Agent) during the quarter:
>\$200	10% of the aggregate funded amount of the Term Loans
\$150 - \$200	\$3.5 million
\$100 - \$150	\$5.0 million
<\$100	\$7.5 million

Commencing with the occurrence of the FDA Approval Event, as tested on the last day of each quarter, actual TTM Revenue for the 12-month period then ended in an amount not less than sixty-five percent (65.00%) of the projections for the same 12-month period as then ended as set forth in the Borrower's financial projections for such period, which financial projections have been approved by Borrower's Board of Directors and are reasonably acceptable to Collateral Agent.

Notwithstanding anything herein to the contrary, Borrower shall not be obligated to comply with the provisions of this Section 6.12 during any fiscal quarter of Borrower if either (i) Borrower's actual TTM Revenue for the 12-month period ended on the last day of the immediately preceding quarter was at least Seventy Five Million Dollars (\$75,000,000.00) or (ii) the Borrower has been cash flow positive for its two most recently completed fiscal quarters.

6.13 Liquidity Covenant. Borrower shall at all times maintain in Collateral Accounts subject to Control Agreements (subject to the timing described in Section 6.6(c)(i) of this Agreement) in favor of Collateral Agent aggregate unrestricted cash balance of not less than Ten percent (10.00%) of the aggregate funded amount of the Term Loans. If, at any given time, the provisions of Section 6.12 require a higher amount of aggregate unrestricted cash balance, the provisions of Section 6.12 shall govern.

7. NEGATIVE COVENANTS

Borrower shall not, and shall not permit any of its Subsidiaries to, do any of the following without the prior written consent of the Required Lenders:

7.1 Dispositions. Convey, sell, lease, transfer, assign, dispose of (collectively, “**Transfer**”), or permit any of its Subsidiaries to Transfer, all or any part of its business or property (including Intellectual Property), except for Transfers (a) of Inventory in the ordinary course of business; (b) of worn out or obsolete Equipment or Equipment no longer used or useful in such Person’s business; (c) in connection with Permitted Liens, Permitted Investments and Permitted Licenses; (d) to the extent constituting a Transfer, any restricted payment explicitly permitted by Section 7.7; (e) having a fair market value not in excess of \$1,000,000 during any fiscal year but not including Intellectual Property; (f) from a Subsidiary to Borrower; and (g) constituting the sale or discount of Accounts or other rights to payment in connection with the compromise or collection thereof, not in excess of \$100,000 during any fiscal year.

7.2 Changes in Business, Management, Ownership, or Business Locations. (a) Engage in or permit any of its Subsidiaries to engage in any business other than the businesses engaged in by Borrower as of the Effective Date or reasonably related thereto; (b) liquidate or dissolve (provided that any Subsidiary may be liquidated or dissolved provided that its assets are Transferred to Borrower); or (c) (i) any Key Person shall cease to be actively engaged in the management of Borrower unless written notice thereof is provided to Collateral Agent and each Lender within ten (10) days of such, or (ii) enter into any transaction or series of related transactions in which (A) the stockholders of Borrower who were not stockholders immediately prior to the first such transaction own more than 50% of the voting stock of Borrower immediately after giving effect to such transaction or related series of such transactions and (B) Borrower ceases to own 100% of the ownership interests of a Subsidiary of Borrower (except pursuant to any Transfer permitted by Section 7.1 or liquidation or dissolution permitted by clause (b) of this Section 7.2. Borrower shall not, without at least fifteen (15) days’ prior written notice to Collateral Agent: (A) add any new offices or business locations, including warehouses (unless such new offices or business locations contain less than Three Hundred Thousand Dollars (\$300,000.00) of book value in assets or property of Borrower or any of its Subsidiaries); (B) change its jurisdiction of organization, (C) change its organizational structure or type, (D) change its legal name, or (E) change any organizational number (if any) assigned by its jurisdiction of organization.

7.3 Mergers or Acquisitions. Merge or consolidate, or permit any of its Subsidiaries to merge or consolidate, with any other Person, or acquire, or permit any of its Subsidiaries to acquire, all or substantially all of the capital stock, shares or property of another Person. A Subsidiary may merge or consolidate into another Subsidiary (provided such surviving Subsidiary is a “co Borrower” hereunder or has provided a secured Guaranty of Borrower’s Obligations hereunder) or with (or into) Borrower provided Borrower is the surviving legal entity, and as long as no Event of Default is occurring prior thereto or arises as a result therefrom.

7.4 Indebtedness. Create, incur, assume, or be liable for any Indebtedness, or permit any Subsidiary to do so, other than Permitted Indebtedness.

7.5 Encumbrance. Create, incur, allow, or suffer any Lien on any of its property, or assign or convey any right to receive income, including the sale of any Accounts, or permit any of its Subsidiaries to do so, except for Permitted Liens, or permit any Collateral not to be subject to the first priority security interest granted herein (except for Permitted Liens), or enter into any agreement, document, instrument or other arrangement (except with or in favor of Collateral Agent, for the ratable benefit of the Lenders) with any Person which directly or indirectly prohibits or has the effect of prohibiting Borrower, or any of its Subsidiaries, from assigning, mortgaging, pledging, granting a security interest in or upon, or encumbering any of Borrower’s or such Subsidiary’s Intellectual Property, except as is otherwise permitted in Section 7.1 hereof and the definition of “**Permitted Liens**”.

7.6 Maintenance of Collateral Accounts. Maintain any Collateral Account except pursuant to the terms of Section 6.6 hereof.

7.7 Restricted Payments. Pay any dividends (other than dividends payable solely in capital stock) or make any distribution or payment in respect of or redeem, retire or purchase any capital stock (other than (a) dividends and distributions paid by Subsidiaries to Borrower; or (b) repurchases pursuant to the terms of employee stock purchase plans, employee restricted stock agreements, stockholder rights plans, director or consultant stock option plans, or similar plans, provided such repurchases do not exceed One Hundred and Fifty Thousand Dollars (\$150,000.00) in the aggregate per fiscal year).

7.8 Investments. Directly or indirectly make any Investment other than Permitted Investments, or permit any of its Subsidiaries to do so.

7.9 Transactions with Affiliates. Directly or indirectly enter into or permit to exist any material transaction with any Affiliate of Borrower or any of its Subsidiaries, except for (a) transactions that are in the ordinary course of Borrower's or such Subsidiary's business, upon fair and reasonable terms that are no less favorable to Borrower or such Subsidiary than would reasonably be obtained in an arm's length transaction with a non-affiliated Person, (b) Subordinated Debt or equity investments by Borrower's investors in Borrower or its Subsidiaries, (c) employment and severance arrangements (including equity incentive plans and employee benefit plans and arrangements) with their respective directors, officers and employees in the ordinary course of business, and (d) transactions solely among Borrower and its Subsidiaries that are otherwise expressly permitted hereunder.

7.10 Subordinated Debt. (a) Make or permit any payment on any Subordinated Debt, except under the terms of the subordination, intercreditor, or other similar agreement to which such Subordinated Debt is subject, or (b) amend any provision in any document relating to the Subordinated Debt which would increase the amount thereof or adversely affect the subordination thereof to Obligations owed to the Lenders.

7.11 Compliance. Become an "investment company" or a company controlled by an "investment company", under the Investment Company Act of 1940, as amended, or undertake as one of its important activities extending credit to purchase or carry margin stock (as defined in Regulation U of the Board of Governors of the Federal Reserve System), or use the proceeds of any Term Loan for that purpose; fail to meet the minimum funding requirements of ERISA, permit a Reportable Event or Prohibited Transaction, as defined in ERISA, to occur; fail to comply with the Federal Fair Labor Standards Act or violate any other law or regulation, if the failure to comply or violation could reasonably be expected to have a Material Adverse Change, or permit any of its Subsidiaries to do so; withdraw or permit any Subsidiary to withdraw from participation in, permit partial or complete termination of, or permit the occurrence of any other event with respect to, any present pension, profit sharing and deferred compensation plan which could reasonably be expected to result in any liability of Borrower or any of its Subsidiaries, including any liability to the Pension Benefit Guaranty Corporation or its successors or any other Governmental Authority.

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

7.13 Material Agreements. Neither Borrower nor any of its Subsidiaries shall (i) materially amend a Material Agreement in a manner materially adverse to the Lenders or (ii) terminate a Material Agreement without giving prompt written notice within five (5) Business Days of such termination.

8. EVENTS OF DEFAULT

Any one of the following shall constitute an event of default (an "**Event of Default**") under this Agreement:

8.1 Payment Default. Borrower fails to (a) make any payment of principal or interest on any Term Loan on its due date, or (b) pay any other Obligations within three (3) Business Days after such Obligations are due and payable (which three (3) Business Day grace period shall not apply to payments due on the Maturity Date or the date of acceleration pursuant to Section 9.1 (a) hereof);

8.2 Covenant Default.

(a) Borrower or any of its Subsidiaries fails or neglects to perform any obligation in Section 2.7, Sections 6.2 (Financial Statements, Reports, Certificates), 6.4 (Taxes), 6.5 (Insurance), 6.6 (Operating Accounts), 6.7 (Protection of Intellectual Property Rights), 6.9 (Landlord Waivers; Bailee Waivers), 6.10 (Creation/Acquisition of Subsidiaries), 6.12 (Financial Covenant) or 6.13 (Liquidity Covenant) or Borrower violates any provision in Section 7; provided, however, in the event that the Borrower fails to comply with the requirements of the financial covenant set forth in Section 6.12, Borrower may cure such breach by means of submitting a new financial

plan to Collateral Agent under which Borrower will breakeven on a cashflow basis prior to Maturity Date (which financial plan must be acceptable to Collateral Agent and approved by Borrower's Board of Directors) no later than thirty (30) days after the occurrence of the breach of the financial covenant and raising, no later than thirty (30) days after the submission of such financial plan to Collateral Agent, such amount of capital from the sale and issuance of its equity securities as required per the new financial plan; provided, that upon such cure the parties shall amend the covenant in Section 6.12 in accordance with the new financial plan which amendment must be acceptable to Collateral Agent and shall, among other things, require Borrower to achieve the revenue projections set forth in the new financial plan; or

(b) Borrower, or any of its Subsidiaries, fails or neglects to perform, keep, or observe any other term, provision, condition, covenant or agreement contained in this Agreement or any Loan Documents, and as to any default (other than those specified in this Section 8) under such other term, provision, condition, covenant or agreement that can be cured, has failed to cure the default within fifteen (15) days after the occurrence thereof; provided, however, that if the default cannot by its nature be cured within the fifteen (15) day period or cannot after diligent attempts by Borrower be cured within such fifteen (15) day period, and such default is likely to be cured within a reasonable time, then Borrower shall have an additional period (which shall not in any case exceed thirty (30) days) to attempt to cure such default, and within such reasonable time period the failure to cure the default shall not be deemed an Event of Default (but no Term Loan shall be made during such cure period);

8.3 Material Adverse Change. A Material Adverse Change has occurred;

8.4 Attachment; Levy; Restraint on Business.

(a) (i) The service of process seeking to attach, by trustee or similar process, any funds of Borrower or any of its Subsidiaries or of any entity under control of Borrower or its Subsidiaries on deposit with any institution at which Borrower or any of its Subsidiaries maintains a Collateral Account, or (ii) a notice of lien, levy, or assessment is filed against Borrower or any of its Subsidiaries or their respective assets by any government agency, and the same under subclauses (i) and (ii) hereof are not, within ten (10) days after the occurrence thereof, discharged or stayed (whether through the posting of a bond or otherwise); and

(b) (i) any material portion of Borrower's or any of its Subsidiaries' assets is attached, seized, levied on, or comes into possession of a trustee or receiver, or (ii) any court order enjoins, restrains, or prevents Borrower or any of its Subsidiaries from conducting any part of its business;

8.5 Insolvency. (a) Borrower becomes Insolvent or Borrower and its Subsidiaries (taken as a whole) become Insolvent; (b) Borrower or any of its Subsidiaries begins an Insolvency Proceeding; or (c) an Insolvency Proceeding is begun against Borrower or any of its Subsidiaries and not dismissed or stayed within forty five (45) days (but no Term Loan shall be extended while Borrower or any Subsidiary is Insolvent and/or until any Insolvency Proceeding is dismissed);

8.6 Other Agreements. There is (a) a default in any agreement to which Borrower or any of its Subsidiaries is a party with a third party or parties resulting in a right by such third party or parties, whether or not exercised, to accelerate the maturity of any Indebtedness in an amount in excess of Two Hundred Fifty Thousand Dollars (\$250,000.00) or that could reasonably be expected to have a Material Adverse Change; or (b) any default under a Material Agreement that permits the counterparty thereto to accelerate the payments owed thereunder.

8.7 Judgments. (a) One or more judgments, orders, or decrees for the payment of money in an amount, individually or in the aggregate, of at least Two Hundred Fifty Thousand Dollars (\$250,000.00) (not paid or covered by independent third party insurance) shall be rendered against Borrower or any of its Subsidiaries and shall remain unsatisfied, unvacated, or unstayed for a period of ten (10) days after the entry thereof or (b) any judgments, orders or decrees rendered against Borrower that could reasonably be expected to result in a Material Adverse Change;

8.8 Misrepresentations. Borrower or any of its Subsidiaries or any Person acting for Borrower or any of its Subsidiaries makes any representation, warranty, or other statement now or later in this Agreement, any Loan Document or in any writing delivered to Collateral Agent and/or Lenders or to induce Collateral Agent and/or the Lenders to enter this Agreement or any Loan Document, and such representation, warranty, or other statement, when taken as a whole, is incorrect in any material respect when made;

8.9 Subordinated Debt. A default or breach occurs under any agreement between Borrower or any of its Subsidiaries and any creditor of Borrower or any of its Subsidiaries that signed a subordination, intercreditor, or other similar agreement with Collateral Agent or the Lenders, or any creditor that has signed such an agreement with Collateral Agent or the Lenders breaches any terms of such agreement;

8.10 [Reserved].

8.11 Governmental Approvals; FDA Action. (a) Any Governmental Approval shall have been revoked, rescinded, suspended, modified in an adverse manner, or not renewed in the ordinary course for a full term and such revocation, rescission, suspension, modification or non-renewal has resulted in or could reasonably be expected to result in a Material Adverse Change; or (b) (i) the FDA, DOJ, or other Governmental Authority initiates a Regulatory Action or any other enforcement action against Borrower or any of its Subsidiaries or any supplier of Borrower or any of its Subsidiaries that causes Borrower or any of its Subsidiaries to recall, withdraw, remove or discontinue manufacturing, distributing, and/or marketing any of its products, even if such action is based on previously disclosed conduct; (ii) the FDA issues a warning letter or Regulatory Action to Borrower or any of its Subsidiaries with respect to any of its activities or products which could reasonably be expected to result in a Material Adverse Change; (iii) Borrower or any of its Subsidiaries conducts a mandatory or voluntary recall which could reasonably be expected to result in liability and expense to Borrower or any of its Subsidiaries of Five Hundred Thousand Dollars (\$500,000.00) or more; (iv) Borrower or any of its Subsidiaries enters into a settlement agreement with the FDA, DOJ, or other Governmental Authority that results in aggregate liability as to any single or related series of transactions, incidents or conditions, of Two Hundred Fifty Thousand Dollars (\$250,000.00) or more, or that could reasonably be expected to result in a Material Adverse Change even if such settlement agreement is based on previously disclosed conduct; or (v) Borrower or any of its Subsidiaries fails to remediate observations identified in an FDA Form 483 notice of inspection observation to Collateral Agent's reasonable satisfaction within six months of receipt; or (vi) the FDA revokes any authorization or permission granted under any Registration, or Borrower or any of its Subsidiaries withdraws any Registration, that could reasonably be expected to result in a Material Adverse Change.

8.12 Lien Priority; Intellectual Property. Any Lien created hereunder or by any other Loan Document shall at any time fail to constitute a valid and perfected Lien on any of the Collateral purported to be secured thereby, subject to no prior or equal Lien, other than Permitted Liens arising as a matter of applicable law. Any Intellectual Property material to Borrower's business shall cease to be validly owned or licensed by Borrower free and clear of any Liens other than Permitted Liens.

9. RIGHTS AND REMEDIES

9.1 Rights and Remedies.

(a) Upon the occurrence and during the continuance of an Event of Default, Collateral Agent may, without notice or demand, do any or all of the following: (i) deliver notice of the Event of Default to Borrower, (ii) by notice to Borrower declare all Obligations immediately due and payable (but if an Event of Default described in Section 8.5 occurs all Obligations shall be immediately due and payable without any action by Collateral Agent or the Lenders) or (iii) by notice to Borrower suspend or terminate the obligations, if any, of the Lenders to advance money or extend credit for Borrower's benefit under this Agreement or under any other agreement between Borrower and Collateral Agent and/or the Lenders (but if an Event of Default described in Section 8.5 occurs all obligations, if any, of the Lenders to advance money or extend credit for Borrower's benefit under this Agreement or under any other agreement between Borrower and Collateral Agent and/or the Lenders shall be immediately terminated without any action by Collateral Agent or the Lenders).

(b) Without limiting the rights of Collateral Agent and the Lenders set forth in Section 9.1(a) above, upon the occurrence and during the continuance of an Event of Default, Collateral Agent shall have the right, without notice or demand, to do any or all of the following:

(i) foreclose upon and/or sell or otherwise liquidate, the Collateral;

(ii) apply to the Obligations any (a) balances and deposits of Borrower that Collateral Agent or any Lender holds or controls, or (b) any amount held or controlled by Collateral Agent or any Lender owing to or for the credit or the account of Borrower; and/or

(iii) commence and prosecute an Insolvency Proceeding or consent to Borrower commencing any Insolvency Proceeding.

(c) Without limiting the rights of Collateral Agent and the Lenders set forth in Sections 9.1(a) and (b) above, upon the occurrence and during the continuance of an Event of Default, Collateral Agent shall have the right, without notice or demand, to do any or all of the following:

(i) settle or adjust disputes and claims directly with Account Debtors for amounts on terms and in any order that Collateral Agent considers advisable, notify any Person owing Borrower money of Collateral Agent's security interest in such funds, and verify the amount of such account;

(ii) make any payments and do any acts it considers necessary or reasonable to protect the Collateral and/or its security interest in the Collateral. Borrower shall assemble the Collateral if Collateral Agent requests and make it available in a location as Collateral Agent reasonably designates. Collateral Agent may enter premises where the Collateral is located, take and maintain possession of any part of the Collateral, and pay, purchase, contest, or compromise any Lien which appears to be prior or superior to its security interest and pay all expenses incurred. Borrower grants Collateral Agent a license to enter and occupy any of its premises, without charge, to exercise any of Collateral Agent's rights or remedies;

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(iii) ship, reclaim, recover, store, finish, maintain, repair, prepare for sale, and/or advertise for sale, the Collateral. Collateral Agent is hereby granted a non exclusive, royalty free license or other right to use, without charge, Borrower's and each of its Subsidiaries' labels, Patents, Copyrights, mask works, rights of use of any name, trade secrets, trade names, Trademarks, service marks, and advertising matter, or any similar property as it pertains to the Collateral, in completing production of, advertising for sale, and selling any Collateral and, in connection with Collateral Agent's exercise of its rights under this Section 9.1, Borrower's and each of its Subsidiaries' rights under all licenses and all franchise agreements inure to Collateral Agent, for the benefit of the Lenders;

(iv) place a "hold" on any account maintained with Collateral Agent or the Lenders and/or deliver a notice of exclusive control, any entitlement order, or other directions or instructions pursuant to any Control Agreement or similar agreements providing control of any Collateral;

(v) demand and receive possession of Borrower's Books;

(vi) appoint a receiver to seize, manage and realize any of the Collateral, and such receiver shall have any right and authority as any competent court will grant or authorize in accordance with any applicable law, including any power or authority to manage the business of Borrower or any of its Subsidiaries; and

(vii) subject to clauses 9.1(a) and (b), exercise all rights and remedies available to Collateral Agent and each Lender under the Loan Documents or at law or equity, including all remedies provided under the Code (including disposal of the Collateral pursuant to the terms thereof).

Notwithstanding any provision of this Section 9.1 to the contrary, upon the occurrence and during the continuance of any Event of Default (that has not been waived by Collateral Agent and Required Lenders), Collateral Agent shall have the right to exercise any and all remedies referenced in this Section 9.1 without the written consent of Required Lenders following the occurrence of an Exigent Circumstance.

9.2 Power of Attorney. Borrower hereby irrevocably appoints Collateral Agent as its lawful attorney in fact, exercisable upon the occurrence and during the continuance of an Event of Default, to: (a) endorse Borrower's or any of its Subsidiaries' name on any checks or other forms of payment or security; (b) sign Borrower's or any of its Subsidiaries' name on any invoice or bill of lading for any Account or drafts against Account Debtors; (c) settle and adjust disputes and claims about the Accounts directly with Account Debtors, for amounts and on terms Collateral Agent determines reasonable; (d) make, settle, and adjust all claims under Borrower's insurance policies; (e) pay, contest or settle any Lien, charge, encumbrance, security interest, and adverse claim in or to the Collateral, or any judgment based thereon, or otherwise take any action to terminate or discharge the same; and (f) transfer the Collateral into the name of Collateral Agent or a third party as the Code or any applicable law permits. Borrower hereby appoints Collateral Agent as its lawful attorney in fact to sign Borrower's or any of its Subsidiaries' name on any documents necessary to perfect or continue the perfection of Collateral Agent's security interest in the Collateral during the continuance of an Event of Default until all Obligations (other

than inchoate indemnity obligations) have been satisfied in full and Collateral Agent and the Lenders are under no further obligation to extend the Term Loan hereunder. Collateral Agent's foregoing appointment as Borrower's or any of its Subsidiaries' attorney in fact, and all of Collateral Agent's rights and powers, coupled with an interest, are irrevocable until all Obligations (other than inchoate indemnity obligations) have been fully repaid and performed and Collateral Agent's and the Lenders' obligation to provide the Term Loan terminates.

9.3 Protective Payments. If Borrower or any of its Subsidiaries fail to obtain the insurance called for by Section 6.5 or fails to pay any premium thereon or fails to pay any other amount which Borrower or any of its Subsidiaries is obligated to pay under this Agreement or any other Loan Document, Collateral Agent may obtain such insurance or make such payment, and all amounts so paid by Collateral Agent are Lenders' Expenses and immediately due and payable, bearing interest at the Default Rate, and secured by the Collateral. Collateral Agent will make reasonable efforts to provide Borrower with notice of Collateral Agent obtaining such insurance or making such payment at the time it is obtained or paid or within a reasonable time thereafter. No such payments by Collateral Agent are deemed an agreement to make similar payments in the future or Collateral Agent's waiver of any Event of Default.

9.4 Application of Payments and Proceeds. Notwithstanding anything to the contrary contained in this Agreement, upon the occurrence and during the continuance of an Event of Default, (a) Borrower irrevocably waives the right to direct the application of any and all payments at any time or times thereafter received by Collateral Agent from or on behalf of Borrower or any of its Subsidiaries of all or any part of the Obligations, and, as between Borrower on the one hand and Collateral Agent and Lenders on the other, Collateral Agent shall have the continuing and exclusive right to apply and to reapply any and all payments received against the Obligations in such manner as Collateral Agent may deem advisable notwithstanding any previous application by Collateral Agent, and (b) the proceeds of any sale of, or other realization upon all or any part of the Collateral shall be applied: first, to the Lenders' Expenses; second, to accrued and unpaid interest on the Obligations (including any interest which, but for the provisions of the United States Bankruptcy Code, would have accrued on such amounts); third, to the principal amount of the Obligations outstanding; and fourth, to any other indebtedness or obligations of Borrower owing to Collateral Agent or any Lender under the Loan Documents. Any balance remaining shall be delivered to Borrower or to whoever may be lawfully entitled to receive such balance or as a court of competent jurisdiction may direct. In carrying out the foregoing, (x) amounts received shall be applied in the numerical order provided until exhausted prior to the application to the next succeeding category, and (y) each of the Persons entitled to receive a payment in any particular category shall receive an amount equal to its pro rata share of amounts available to be applied pursuant thereto for such category. Any reference in this Agreement to an allocation between or sharing by the Lenders of any right, interest or obligation "ratably," "proportionally" or in similar terms shall refer to Pro Rata Share unless expressly provided otherwise. Collateral Agent, or if applicable, each Lender, shall promptly remit to the other Lenders such sums as may be necessary to ensure the ratable repayment of each Lender's portion of any Term Loan and the ratable distribution of interest, fees and reimbursements paid or made by Borrower. Notwithstanding the foregoing, a Lender receiving a scheduled payment shall not be responsible for determining whether the other Lenders also received their scheduled payment on such date; provided, however, if it is later determined that a Lender received more than its ratable share of scheduled payments made on any date or dates, then such Lender shall remit to Collateral Agent or other Lenders such sums as may be necessary to ensure the ratable payment of such scheduled payments, as instructed by Collateral Agent. If any payment or distribution of any kind or character, whether in cash, properties or securities, shall be received by a Lender in excess of its ratable share, then the portion of such payment or distribution in excess of such Lender's ratable share shall be received by such Lender in trust for and shall be promptly paid over to the other Lender for application to the payments of amounts due on the other Lenders' claims. To the extent any payment for the account of Borrower is required to be returned as a voidable transfer or otherwise, the Lenders shall contribute to one another as is necessary to ensure that such return of payment is on a pro rata basis. If any Lender shall obtain possession of any Collateral, it shall hold such Collateral for itself and as agent and bailee for Collateral Agent and other Lenders for purposes of perfecting Collateral Agent's security interest therein.

9.5 Liability for Collateral. So long as Collateral Agent and the Lenders comply with reasonable banking practices regarding the safekeeping of the Collateral in the possession or under the control of Collateral Agent and the Lenders, Collateral Agent and the Lenders shall not be liable or responsible for: (a) the safekeeping of the Collateral; (b) any loss or damage to the Collateral; (c) any diminution in the value of the Collateral; or (d) any act or default of any carrier, warehouseman, bailee, or other Person. Borrower bears all risk of loss, damage or destruction of the Collateral.

9.6 No Waiver; Remedies Cumulative. Failure by Collateral Agent or any Lender, at any time or times, to require strict performance by Borrower of any provision of this Agreement or any other Loan Document shall not waive, affect, or diminish any right of Collateral Agent or any Lender thereafter to demand strict performance and compliance herewith or therewith. No waiver hereunder shall be effective unless signed by Collateral Agent and the Required Lenders and then is only effective for the specific instance and

purpose for which it is given. The rights and remedies of Collateral Agent and the Lenders under this Agreement and the other Loan Documents are cumulative. Collateral Agent and the Lenders have all rights and remedies provided under the Code, any applicable law, by law, or in equity. The exercise by Collateral Agent or any Lender of one right or remedy is not an election, and Collateral Agent's or any Lender's waiver of any Event of Default is not a continuing waiver. Collateral Agent's or any Lender's delay in exercising any remedy is not a waiver, election, or acquiescence.

9.7 Demand Waiver. Borrower waives, to the fullest extent permitted by law, demand, notice of default or dishonor, notice of payment and nonpayment, notice of any default, nonpayment at maturity, release, compromise, settlement, extension, or renewal of accounts, documents, instruments, chattel paper, and guarantees held by Collateral Agent or any Lender on which Borrower or any Subsidiary is liable.

10. NOTICES

All notices, consents, requests, approvals, demands, or other communication (collectively, "**Communication**") by any party to this Agreement or any other Loan Document must be in writing and shall be deemed to have been validly served, given, or delivered: (a) upon the earlier of actual receipt and three (3) Business Days after deposit in the U.S. mail, first class, registered or certified mail return receipt requested, with proper postage prepaid; (b) upon transmission, when sent by facsimile transmission; (c) one (1) Business Day after deposit with a reputable overnight courier with all charges prepaid; or (d) when delivered, if hand delivered by messenger, all of which shall be addressed to the party to be notified and sent to the address, facsimile number, or email address indicated below. Any of Collateral Agent, Lender or Borrower may change its mailing address or facsimile number by giving the other party written notice thereof in accordance with the terms of this Section 10.

If to Borrower: CELCUITY, INC.
 16305 – 36th Avenue North
 Suite 100
 Minneapolis, MN 55446
 Attn: Chief Financial Officer
 Email: [Omitted]

with a copy (which
shall
not constitute notice) Fredrikson & Byron, P.A.
to:

200 South Sixth Street, Suite 4000
Minneapolis, MN 55402
Attn: Brad Wallace
Fax: (612) 492-7077
Email: [Omitted]

If to Collateral
Agent: INNOVATUS LIFE SCIENCES
 LENDING FUND I, LP
 777 Third Avenue, 25th Floor
 New York, NY 10017
 Attn: Claes Ekstrom
 Email: [Omitted]

with a copy (which
shall
not constitute notice) Greenberg Traurig, LLP
to:

One International Place
Boston, MA 02110
Attn: Abdullah Malik

11. CHOICE OF LAW, VENUE AND JURY TRIAL WAIVER

11.1 Waiver of Jury Trial. EACH OF BORROWER, COLLATERAL AGENT AND LENDERS UNCONDITIONALLY WAIVES ANY AND ALL RIGHT TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION BASED UPON OR ARISING OUT OF THIS AGREEMENT, ANY OF THE OTHER LOAN DOCUMENTS, ANY OF THE INDEBTEDNESS SECURED HEREBY, ANY DEALINGS AMONG BORROWER, COLLATERAL AGENT AND/OR LENDERS RELATING TO THE SUBJECT MATTER OF THIS TRANSACTION OR ANY RELATED TRANSACTIONS, AND/OR THE RELATIONSHIP THAT IS BEING ESTABLISHED AMONG BORROWER, COLLATERAL AGENT AND/OR LENDERS. THE SCOPE OF THIS WAIVER IS INTENDED TO BE ALL ENCOMPASSING OF ANY AND ALL DISPUTES THAT MAY BE FILED IN ANY COURT. THIS WAIVER IS IRREVOCABLE. THIS WAIVER MAY NOT BE MODIFIED EITHER ORALLY OR IN WRITING. THE WAIVER ALSO SHALL APPLY TO ANY SUBSEQUENT AMENDMENTS, RENEWALS, SUPPLEMENTS OR MODIFICATIONS TO THIS AGREEMENT, ANY OTHER LOAN DOCUMENTS, OR TO ANY OTHER DOCUMENTS OR AGREEMENTS RELATING TO THIS TRANSACTION OR ANY RELATED TRANSACTION. THIS AGREEMENT MAY BE FILED AS A WRITTEN CONSENT TO A TRIAL BY THE COURT.

11.2 Governing Law and Jurisdiction.

(a) THIS AGREEMENT, THE OTHER LOAN DOCUMENTS (EXCLUDING THOSE LOAN DOCUMENTS THAT BY THEIR OWN TERMS ARE EXPRESSLY GOVERNED BY THE LAWS OF ANOTHER JURISDICTION) AND THE RIGHTS AND OBLIGATIONS OF THE PARTIES HEREUNDER AND THEREUNDER SHALL IN ALL RESPECTS BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH, THE INTERNAL LAWS OF THE STATE OF NEW YORK (WITHOUT REGARD TO THE CONFLICT OF LAWS PRINCIPLES THAT WOULD RESULT IN THE APPLICATION OF ANY LAWS OTHER THAN THE LAWS OF THE STATE OF NEW YORK), INCLUDING ALL MATTERS OF CONSTRUCTION, VALIDITY AND PERFORMANCE, REGARDLESS OF THE LOCATION OF THE COLLATERAL, PROVIDED, HOWEVER, THAT IF THE LAWS OF ANY JURISDICTION OTHER THAN NEW YORK SHALL GOVERN IN REGARD TO THE VALIDITY, PERFECTION OR EFFECT OF PERFECTION OF ANY LIEN OR IN REGARD TO PROCEDURAL MATTERS AFFECTING ENFORCEMENT OF ANY LIENS IN COLLATERAL, SUCH LAWS OF SUCH OTHER JURISDICTIONS SHALL CONTINUE TO APPLY TO THAT EXTENT.

(b) Submission to Jurisdiction. Any legal action or proceeding with respect to the Loan Documents shall be brought exclusively in the courts of the State of New York located in the City of New York, Borough of Manhattan, or of the United States of America for the Southern District of New York and, by execution and delivery of this Agreement, Borrower hereby accepts for itself and in respect of its Property, generally and unconditionally, the jurisdiction of the aforesaid courts. Notwithstanding the foregoing, Collateral Agent and Lenders shall have the right to bring any action or proceeding against Borrower (or any property of Borrower) in the court of any other jurisdiction Collateral Agent or Lenders deem necessary or appropriate in order to realize on the Collateral or other security for the Obligations. The parties hereto hereby irrevocably waive any objection, including any objection to the laying of venue or based on the grounds of forum non conveniens, that any of them may now or hereafter have to the bringing of any such action or proceeding in such jurisdictions.

(c) Service of Process. Borrower irrevocably waives personal service of any and all legal process, summons, notices and other documents and other service of process of any kind and consents to such service in any suit, action or proceeding brought in the United States of America with respect to or otherwise arising out of or in connection with any Loan Document by any means permitted by applicable requirements of law, including by the mailing thereof (by registered or certified mail, postage prepaid) to the address of Borrower specified herein (and shall be effective when such mailing shall be effective, as provided therein). Borrower agrees that a final judgment in any such action or proceeding shall be conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by law.

(d) Non-exclusive Jurisdiction. Nothing contained in this Section 11.2 shall affect the right of Collateral Agent or Lenders to serve process in any other manner permitted by applicable requirements of law or commence legal proceedings or otherwise proceed against Borrower in any other jurisdiction.

12. GENERAL PROVISIONS

12.1 Successors and Assigns. This Agreement binds and is for the benefit of the successors and permitted assigns of each party. Borrower may not transfer, pledge or assign this Agreement or any rights or obligations under it without Collateral Agent's prior written consent (which may be granted or withheld in Collateral Agent's discretion, subject to Section 12.5). The Lenders have the right, without the consent of or notice to Borrower, to sell, transfer, assign, pledge, negotiate, or grant participation in (any such sale, transfer, assignment, negotiation, or grant of a participation, a "**Lender Transfer**") all or any part of, or any interest in, the Lenders' obligations, rights, and benefits under this Agreement and the other Loan Documents. Borrower and Collateral Agent shall be entitled to continue to deal solely and directly with such Lender in connection with the interests so assigned until Collateral Agent shall have received and accepted an effective assignment agreement in form satisfactory to Collateral Agent executed, delivered and fully completed by the applicable parties thereto, and shall have received such other information regarding such transferee as Collateral Agent reasonably shall require. Notwithstanding anything to the contrary contained herein, so long as no Event of Default has occurred and is continuing, no Lender Transfer (other than a Lender Transfer in connection with (i) assignments by a Lender due to a forced divestiture at the request of any regulatory agency; or (ii) upon the occurrence of a default, event of default or similar occurrence with respect to a Lender's own financing or securitization transactions) shall be permitted, without Borrower's consent, to any Person which is a direct competitor of Borrower or a vulture hedge fund, each as determined by Collateral Agent.

12.2 Indemnification. Borrower agrees to indemnify, defend and hold Collateral Agent and the Lenders and their respective directors, officers, employees, consultants, agents, attorneys, or any other Person affiliated with or representing Collateral Agent or the Lenders (each, an "**Indemnified Person**") harmless against: (a) all obligations, demands, claims, and liabilities (collectively, "**Claims**") asserted by any other party in connection with; related to; following; or arising from, out of or under, the transactions contemplated by the Loan Documents; and (b) all losses or Lenders' Expenses incurred, or paid by Indemnified Person in connection with; related to; following; or arising from, out of or under, the transactions contemplated by the Loan Documents between Collateral Agent, and/or the Lenders and Borrower (including reasonable documented attorneys' fees and expenses), except for Claims and/or losses directly caused by such Indemnified Person's gross negligence or willful misconduct. Borrower hereby further indemnifies, defends and holds each Indemnified Person harmless from and against any and all liabilities, obligations, losses, damages, penalties, actions, judgments, suits, claims, costs, expenses and disbursements of any kind or nature whatsoever (including the fees and disbursements of counsel for such Indemnified Person) in connection with any investigative, response, remedial, administrative or judicial matter or proceeding, whether or not such Indemnified Person shall be designated a party thereto and including any such proceeding initiated by or on behalf of Borrower, and the reasonable and documented expenses of investigation by engineers, environmental consultants and similar technical personnel and any commission, fee or compensation claimed by any broker (other than any broker retained by Collateral Agent or Lenders) asserting any right to payment for the transactions contemplated hereby which may be imposed on, incurred by or asserted against such Indemnified Person as a result of or in connection with the transactions contemplated hereby and the use or intended use of the proceeds of the loan proceeds except for liabilities, obligations, losses, damages, penalties, actions, judgments, suits, claims, costs, expenses and disbursements directly caused by such Indemnified Person's gross negligence or willful misconduct.

12.3 Severability of Provisions. Each provision of this Agreement is severable from every other provision in determining the enforceability of any provision.

12.4 Correction of Loan Documents. Collateral Agent may correct patent errors and fill in any blanks in this Agreement and the other Loan Documents consistent with the agreement of the parties so long as Collateral Agent provides Borrower with written notice of such correction and allows Borrower at least ten (10) days to object to such correction. In the event of such objection, such correction shall not be made except by an amendment signed by Collateral Agent, the Lenders and Borrower.

12.5 Amendments in Writing; Integration. (a) No amendment, modification, termination or waiver of any provision of this Agreement or any other Loan Document, no approval or consent thereunder, or any consent to any departure by Borrower or any of its Subsidiaries therefrom, shall in any event be effective unless the same shall be in writing and signed by Borrower, Collateral Agent and the Required Lenders provided that:

(i) no such amendment, waiver or other modification that would have the effect of increasing or reducing a Lender's Term Loan Commitment or Commitment Percentage shall be effective as to such Lender without such Lender's written consent;

(ii) no such amendment, waiver or modification that would affect the rights and duties of Collateral Agent shall be effective without Collateral Agent's written consent or signature; and

(iii) no such amendment, waiver or other modification shall, unless signed by all the Lenders directly affected thereby, (A) reduce the principal of, rate of interest on or any fees with respect to any Term Loan or forgive any principal, interest (other than default interest) or fees (other than late charges) with respect to any Term Loan (B) postpone the date fixed for, or waive, any payment of principal of any Term Loan or of interest on any Term Loan (other than default interest) or any fees provided for hereunder (other than late charges or for any termination of any commitment); (C) change the definition of the term "Required Lenders" or the percentage of Lenders which shall be required for the Lenders to take any action hereunder; (D) release all or substantially all of any material portion of the Collateral, authorize Borrower to sell or otherwise dispose of all or substantially all or any material portion of the Collateral or release any Guarantor of all or any portion of the Obligations or its guaranty obligations with respect thereto, except, in each case with respect to this clause (D), as otherwise may be expressly permitted under this Agreement or the other Loan Documents (including in connection with any disposition permitted hereunder); (E) amend, waive or otherwise modify this Section 12.5 or the definitions of the terms used in this Section 12.5 insofar as the definitions affect the substance of this Section 12.5; (F) consent to the assignment, delegation or other transfer by Borrower of any of its rights and obligations under any Loan Document or release Borrower of its payment obligations under any Loan Document, except, in each case with respect to this clause (F), pursuant to a merger or consolidation permitted pursuant to this Agreement; (G) amend any of the provisions of Section 9.4 or amend any of the definitions of Pro Rata Share, Term Loan Commitment, Commitment Percentage or that provide for the Lenders to receive their Pro Rata Shares of any fees, payments, setoffs or proceeds of Collateral hereunder; (H) subordinate the Liens granted in favor of Collateral Agent securing the Obligations; or (I) amend any of the provisions of Section 12.5. It is hereby understood and agreed that all Lenders shall be deemed directly affected by an amendment, waiver or other modification of the type described in the preceding clauses (C), (D), (E), (F), (G) and (H) of the immediately preceding sentence.

(b) Other than as expressly provided for in Section 12.5(a)(i) (iii), Collateral Agent may, if requested by the Required Lenders, from time to time designate covenants in this Agreement less restrictive by notification to a representative of Borrower.

(c) This Agreement and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements with respect to such subject matter. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Agreement and the Loan Documents merge into this Agreement and the Loan Documents.

12.6 Counterparts. This Agreement may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Agreement.

12.7 Survival. All covenants, representations and warranties made in this Agreement continue in full force and effect until this Agreement has terminated pursuant to its terms and all Obligations (other than inchoate indemnity obligations and any other obligations which, by their terms, are to survive the termination of this Agreement) have been satisfied. The obligation of Borrower in Section 12.2 to indemnify each Lender and Collateral Agent, as well as the confidentiality provisions in Section 12.8 below, shall survive until the statute of limitations with respect to such claim or cause of action shall have run.

12.8 Confidentiality. In handling any confidential information of Borrower, the Lenders and Collateral Agent shall exercise the same degree of care that it exercises for their own proprietary information, but disclosure of information may be made: (a) subject to the terms and conditions of this Agreement, to the Lenders' and Collateral Agent's Subsidiaries or Affiliates, who have been advised about the confidential nature of such information and directed to keep such information confidential; (b) to prospective transferees (other than those identified in (a) above) or purchasers of any interest in the Term Loan (provided, however, (i) if, at the applicable time, an Event of Default has occurred and is outstanding, the Lenders and Collateral Agent shall advise such prospective transferee or purchaser about the confidential nature of such information and (ii) if, at the applicable time, no Event of Default has occurred and is continuing, obtain such prospective transferee's or purchaser's agreement to the terms of this provision or to similar confidentiality terms); (c) as required by law, regulation, subpoena, or other order; (d) to Lenders' or Collateral Agent's regulators or as otherwise required in connection with an examination or audit (provided such regulatory authority shall be advised about the confidential nature of such information); (e) as Collateral Agent reasonably considers appropriate in exercising remedies under the Loan Documents; and (f) to third party service providers of the Lenders and/or Collateral Agent so long as such service providers have executed a confidentiality agreement or have agreed to similar confidentiality terms with the Lenders and Collateral Agent with terms no less restrictive than those contained herein. Confidential information does not include information that either: (i) is in the public domain or in the Lenders' and/or Collateral Agent's possession when disclosed to the Lenders and/or Collateral Agent, or becomes part of the public domain after disclosure to the Lenders and/or Collateral Agent at no fault of the Lenders or the Collateral Agent; or (ii) is disclosed to the Lenders and/or Collateral Agent by a third party, if the Lenders and/or Collateral Agent does not know that the third party is prohibited from

disclosing the information. Collateral Agent and the Lenders may use confidential information for any purpose, including, without limitation, for the development of client databases, reporting purposes, and market analysis. The provisions of the immediately preceding sentence shall survive the termination of this Agreement. The agreements provided under this Section 12.8 supersede all prior agreements, understanding, representations, warranties, and negotiations between the parties about the subject matter of this Section 12.8.

12.9 Right of Set Off. Borrower hereby grants to Collateral Agent and to each Lender, a lien, security interest and right of set off as security for all Obligations to Collateral Agent and each Lender hereunder, whether now existing or hereafter arising upon and against all deposits, credits, collateral and property, now or hereafter in the possession, custody, safekeeping or control of Collateral Agent or the Lenders or any entity under the control of Collateral Agent or the Lenders (including a Collateral Agent affiliate) or in transit to any of them. At any time after the occurrence and during the continuance of an Event of Default, without demand or notice, Collateral Agent or the Lenders may set off the same or any part thereof and apply the same to any liability or obligation of Borrower even though unmatured and regardless of the adequacy of any other collateral securing the Obligations. ANY AND ALL RIGHTS TO REQUIRE COLLATERAL AGENT TO EXERCISE ITS RIGHTS OR REMEDIES WITH RESPECT TO ANY OTHER COLLATERAL WHICH SECURES THE OBLIGATIONS, PRIOR TO EXERCISING ITS RIGHT OF SETOFF WITH RESPECT TO SUCH DEPOSITS, CREDITS OR OTHER PROPERTY OF BORROWER ARE HEREBY KNOWINGLY, VOLUNTARILY AND IRREVOCABLY WAIVED BY BORROWER.

12.10 Cooperation of Borrower. If necessary, Borrower agrees to (i) execute any documents reasonably required to effectuate and acknowledge each assignment of a Term Loan Commitment or Term Loan to an assignee in accordance with Section 12.1, (ii) make Borrower's management available to meet with Collateral Agent and prospective participants and assignees of Term Loan Commitments (which meetings shall be conducted no more often than twice every twelve months unless an Event of Default has occurred and is continuing), and (iii) assist Collateral Agent or the Lenders in the preparation of information relating to the financial affairs of Borrower as any prospective participant or assignee of a Term Loan Commitment or Term Loan reasonably may request. Subject to the provisions of Section 12.8, Borrower authorizes each Lender to disclose to any prospective participant or assignee of a Term Loan Commitment, any and all information in such Lender's possession concerning Borrower and its financial affairs which has been delivered to such Lender by or on behalf of Borrower pursuant to this Agreement, or which has been delivered to such Lender by or on behalf of Borrower in connection with such Lender's credit evaluation of Borrower prior to entering into this Agreement.

12.11 Public Announcement. Borrower hereby agrees that Collateral Agent and each Lender may make a public announcement of the transactions contemplated by this Agreement, and may publicize the same in marketing materials, newspapers and other publications, and otherwise, and in connection therewith may use Borrower's name, tradenames and logos.

12.12 Collateral Agent and Lender Agreement. Collateral Agent and each Lender hereby agree to the terms and conditions set forth on Annex I attached hereto. Borrower acknowledges and agrees to the terms and conditions set forth on Annex I attached hereto.

13. DEFINITIONS

As used in this Agreement, the following terms have the following meanings:

"Account" is any "account" as defined in the Code with such additions to such term as may hereafter be made, and includes, without limitation, all accounts receivable and other sums owing to Borrower.

"Account Debtor" is any "account debtor" as defined in the Code with such additions to such term as may hereafter be made under the Code.

"Affiliate" of any Person is a Person that owns or controls directly or indirectly the Person, any Person that controls or is controlled by or is under common control with the Person, and each of that Person's senior executive officers, directors, partners if such Person is a partnership and, for any Person that is a limited liability company, that Person's managers and members.

“**Amortization Date**” is (i) May 1, 2024, if the I/O Extension Event does not occur and (ii) May 1, 2025, if the I/O Extension Event occurs.

“**Anti Terrorism Laws**” are any laws relating to terrorism or money laundering, including without limitation Executive Order No. 13224 (effective September 24, 2001), the USA PATRIOT Act, the laws comprising or implementing the Bank Secrecy Act, and the laws administered by OFAC.

“**Basic Rate**” is with respect to each Term Loan, the floating per annum rate of interest (based on a year of three hundred sixty five (365) days) equal to the sum of (a) the greater of (i) Prime Rate, subject to Section 2.3(f), or (ii) Three and twenty-five hundredths percent (3.25%), and (b) Five and Seventy Hundredths percent (5.70%).

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

“**Borrower’s Books**” are Borrower’s or any of its Subsidiaries’ books and records including ledgers, federal, and state tax returns, records regarding Borrower’s or its Subsidiaries’ assets or liabilities, the Collateral, business operations or financial condition, and all computer programs or storage or any equipment containing such information.

“**Business Day**” is any day that is not a Saturday, Sunday or a day on which banks in New York are not open for the conduct of their commercial banking business.

“**Cash Burn**” is the cash used by Borrower in its operations and capital expenditures.

“**Cash Equivalents**” are (a) marketable direct obligations issued or unconditionally guaranteed by the United States or any agency or any State thereof having maturities of not more than one (1) year from the date of acquisition; (b) commercial paper maturing no more than one (1) year after its creation and having the highest rating from either Standard & Poor’s Ratings Group or Moody’s Investors Service, Inc., (c) certificates of deposit maturing no more than one (1) year after issue provided that the account in which any such certificate of deposit is maintained is subject to a Control Agreement in favor of Collateral Agent and (d) solely with respect to any Subsidiary not organized in the United States, any equivalent of Cash Equivalents referred to in clauses (a) through (c) of this definition, denominated in the foreign currency that is the local currency where such Subsidiary is organized or has its principal place of business which are comparable in tenor and credit quality to those referred to in clauses (a) through (c) above and customarily used in the ordinary course of business by similar companies for cash management purposes in the relevant jurisdiction to the extent reasonably required in connection with any business conducted by such Subsidiary in such jurisdiction.

“**Code**” is the Uniform Commercial Code, as the same may, from time to time, be enacted and in effect in the State of New York; provided, that, to the extent that the Code is used to define any term herein or in any Loan Document and such term is defined differently in different Articles or Divisions of the Code, the definition of such term contained in Article or Division 9 shall govern; provided further, that in the event that, by reason of mandatory provisions of law, any or all of the attachment, perfection, or priority of, or remedies with respect to, Collateral Agent’s Lien on any Collateral is governed by the Uniform Commercial Code in effect in a jurisdiction other than the State of New York, the term “**Code**” shall mean the Uniform Commercial Code as enacted and in effect in such other jurisdiction solely for purposes of the provisions thereof relating to such attachment, perfection, priority, or remedies and for purposes of definitions relating to such provisions.

“**Collateral**” is any and all properties, rights and assets of Borrower described on Exhibit A.

“**Collateral Account**” is any Deposit Account, Securities Account, or Commodity Account, or any other bank account maintained by Borrower or any Subsidiary at any time.

“**Commitment Percentage**” is set forth in Schedule 1.1, as amended from time to time.

“**Commodity Account**” is any “commodity account” as defined in the Code with such additions to such term as may hereafter be made under the Code.

“**Compliance Certificate**” is that certain certificate in substantially the form attached hereto as Exhibit C.

“**Contingent Obligation**” is, for any Person, any direct or indirect liability, contingent or not, of that Person for (a) any indebtedness, lease, dividend, letter of credit or other obligation of another Person such as an obligation directly or indirectly guaranteed, endorsed, co made, discounted or sold with recourse by that Person, or for which that Person is directly or indirectly liable; (b) any obligations for undrawn letters of credit for the account of that Person; and (c) all obligations from any interest rate, currency or commodity swap agreement, interest rate cap or collar agreement, or other agreement or arrangement designated to protect a Person against fluctuation in interest rates, currency exchange rates or commodity prices; but “Contingent Obligation” does not include endorsements in the ordinary course of business. The amount of a Contingent Obligation is the stated or determined amount of the primary obligation for which the Contingent Obligation is made or, if not determinable, the maximum reasonably anticipated liability for it determined by the Person in good faith; but the amount may not exceed the maximum of the obligations under any guarantee or other support arrangement.

“**Control Agreement**” is any control agreement entered into among the depository institution at which Borrower or any of its Subsidiaries maintains a Deposit Account or the securities intermediary or commodity intermediary at which Borrower or any of its Subsidiaries maintains a Securities Account or a Commodity Account, Borrower and such Subsidiary, and Collateral Agent pursuant to which Collateral Agent, for the benefit of the Lenders, obtains “control” (within the meaning of the Code) over such Deposit Account, Securities Account, or Commodity Account.

“**Copyrights**” are any and all copyright rights, copyright applications, copyright registrations and like protections in each work of authorship and derivative work thereof, whether published or unpublished and whether or not the same also constitutes a trade secret.

“**Deposit Account**” is any “deposit account” as defined in the Code with such additions to such term as may hereafter be made.

“**Designated Deposit Account**” is Borrower’s bank account identified to Collateral Agent in writing prior to the Funding Date of the Term A Loan and which account must be subject to a Control Agreement in favor of Collateral Agent at all times.

“**Disbursement Letter**” is that certain form attached hereto as EXHIBIT B-2.

“**DOJ**” means the U.S. Department of Justice or any successor thereto or any other comparable Governmental Authority.

“**Dollars**,” “dollars” and “\$” each mean lawful money of the United States.

“**Equipment**” is all “equipment” as defined in the Code with such additions to such term as may hereafter be made, and includes without limitation all machinery, fixtures, goods, vehicles (including motor vehicles and trailers), and any interest in any of the foregoing.

“**ERISA**” is the Employee Retirement Income Security Act of 1974, as amended, and its regulations.

“**Exigent Circumstance**” means any event or circumstance that, in the reasonable judgment of Collateral Agent, imminently threatens the ability of Collateral Agent to realize upon all or any material portion of the Collateral, such as, without limitation, fraudulent removal, concealment, or abscondment thereof, destruction or material waste thereof, or failure of Borrower or any of its Subsidiaries after reasonable demand to maintain or reinstate adequate casualty insurance coverage, or which, in the judgment of Collateral Agent, could reasonably be expected to result in a material diminution in value of the Collateral.

“**Facility Fee**” is a fee due on the Funding Date of each Term Loan, equal to 1.00% of the amount of Term Loan funded on such Funding Date, payable to Lenders in accordance with their Pro Rata Shares with respect to such Term Loan.

“**FDA**” means the U.S. Food and Drug Administration or any successor thereto or any other comparable Governmental Authority.

“**FDA Approval Event**” is the final approval by the FDA of a companion diagnostics test involving the Borrower’s CELsignia diagnostics by the FDA.

“**Final Fee**” is a payment (in addition to and not a substitution for the regular monthly payments of principal plus accrued interest or any other fee payable hereunder) due on the earliest to occur of (a) the Maturity Date, or (b) the acceleration of any Term Loan, or (c) the prepayment of the Term Loan pursuant to Section 2.2(c) or (d), in each case equal to Four and one-half percent (4.50%) *multiplied* by the aggregate amount of the Term Loans funded and not converted to Borrower Equity pursuant to Section 2.7, payable to Lenders in accordance with their respective Pro Rata Shares. For the avoidance of doubt, the calculation of any Final Fee payment shall not include the principal amount prepaid in accordance with the second paragraph of Section 2.2(d) if a Final Fee payment based on such principal amount was made at the time of such prepayment.

“**Foreign Currency**” means lawful money of a country other than the United States.

“**Foreign Subsidiary**” is a Subsidiary that is not an entity organized under the laws of the United States or any state thereof.

“**Funding Date**” is any date on which the Term Loan is made to or on account of Borrower which shall be a Business Day.

“**GAAP**” is generally accepted accounting principles set forth in the opinions and pronouncements of the Accounting Principles Board of the American Institute of Certified Public Accountants and statements and pronouncements of the Financial Accounting Standards Board or in such other statements by such other Person as may be approved by a significant segment of the accounting profession in the United States, which are applicable to the circumstances as of the date of determination.

“**General Intangibles**” are all “general intangibles” as defined in the Code in effect on the date hereof with such additions to such term as may hereafter be made, and includes without limitation, all copyright rights, copyright applications, copyright registrations and like protections in each work of authorship and derivative work, whether published or unpublished, any patents, trademarks, service marks and, to the extent permitted under applicable law, any applications therefor, whether registered or not, any trade secret rights, including any rights to unpatented inventions, payment intangibles, royalties, contract rights, goodwill, franchise agreements, purchase orders, customer lists, route lists, telephone numbers, domain names, claims, income and other tax refunds, security and other deposits, options to purchase or sell real or personal property, rights in all litigation presently or hereafter pending (whether in contract, tort or otherwise), insurance policies (including without limitation key man, property damage, and business interruption insurance), payments of insurance and rights to payment of any kind.

“**Governmental Approval**” is any consent, authorization, approval, order, license, franchise, permit, certificate, accreditation, registration, filing or notice, of, issued by, from or to, or other act by or in respect of, any Governmental Authority.

“**Governmental Authority**” is any nation or government, any state or other political subdivision thereof, any agency, authority, instrumentality, regulatory body (including, without limitation, the FDA and any state board of pharmacy or state pharmacy licensing authority), court, central bank or other entity exercising executive, legislative, judicial, taxing, regulatory or administrative functions of or pertaining to government, any securities exchange and any self regulatory organization.

“**Guarantor**” is any Person providing a Guaranty in favor of Collateral Agent for the benefit of the Lenders.

“**Guaranty**” is any guarantee of all or any part of the Obligations, as the same may from time to time be amended, restated, modified or otherwise supplemented.

“**Indebtedness**” is (a) indebtedness for borrowed money or the deferred price of property or services, such as reimbursement and other obligations for surety bonds and letters of credit, (b) obligations evidenced by notes, bonds, debentures or similar instruments, (c) capital lease obligations, and (d) Contingent Obligations.

“**Insolvency Proceeding**” is any proceeding by or against any Person under the United States Bankruptcy Code, or any other bankruptcy or insolvency law, including assignments for the benefit of creditors, compositions or proceedings seeking reorganization, arrangement, or other relief.

“**Insolvent**” means not Solvent.

“**Intellectual Property**” means all of Borrower’s or any of its Subsidiaries’ right, title and interest in and to the following:

(a) its Copyrights, Trademarks and Patents;

(b) any and all trade secrets and trade secret rights, including, without limitation, any rights to unpatented inventions, know how, operating manuals;

(c) any and all source code;

(d) any and all design rights which may be available to Borrower;

(e) any and all claims for damages by way of past, present and future infringement of any of the foregoing, with the right, but not the obligation, to sue for and collect such damages for said use or infringement of the Intellectual Property rights identified above;

(f) all amendments, renewals and extensions of any of the Copyrights, Trademarks or Patents; and

(g) all licenses, sublicenses or other contracts under which Borrower or any Subsidiary is granted rights by third parties in any Intellectual Property asset.

“Inventory” is all “inventory” as defined in the Code in effect on the date hereof with such additions to such term as may hereafter be made under the Code, and includes without limitation all merchandise, raw materials, parts, supplies, packing and shipping materials, work in process and finished products, including without limitation such inventory as is temporarily out of any Person’s custody or possession or in transit and including any returned goods and any documents of title representing any of the above.

“Investment” is any beneficial ownership interest in any Person (including stock, partnership interest or other securities), and any loan, advance or capital contribution to any Person.

“I/O Extension Event” is (i) the occurrence of the FDA Approval Event prior to the third anniversary of the Effective Date and (ii) if on third anniversary of the Effective Date, development of Gedatolisib (PF-05212384, PKI-587) (to be in-licensed from Pfizer, Inc. by Borrower) is still ongoing, as per Collateral Agent’s determination, Borrower has received after the Effective Date and prior to the third anniversary of the Effective Date sufficient unrestricted net cash proceeds from the sale and issuance of its equity securities to fully fund the Phase 3 clinical trials of its Gedatolisib.

“IP Security Agreement” is that certain Intellectual Property Security Agreement executed and delivered by Borrower to Collateral Agent and dated as of the Effective Date, as may be amended, restated, or otherwise modified or supplemented from time to time.

“Key Person” is each of Borrower’s (i) Chief Executive Officer, who is Brian Sullivan on the Effective Date, (ii) Chief Financial Officer, who is Vicky Hahne as of the Effective Date and (iii) Chief Science Officer, who is Lance Laing as of the Effective Date.

“Knowledge” means to the “best of” Borrower’s knowledge, or with a similar qualification, knowledge or awareness means the actual knowledge, after reasonable investigation, of the Responsible Officers.

“Lender” is any one of the Lenders.

“Lenders” are the Persons identified on Schedule 1.1 hereto and each assignee that becomes a party to this Agreement pursuant to Section 12.1.

“Lenders’ Expenses” are all audit fees and expenses, costs, and expenses (including reasonable and documented attorneys’ fees and expenses, as well as appraisal fees, fees incurred on account of lien searches, inspection fees, and filing fees) for preparing, amending, negotiating, administering, defending and enforcing the Loan Documents (including, without limitation, those incurred in connection with appeals or Insolvency Proceedings) or otherwise incurred by Collateral Agent and/or the Lenders in connection with the Loan Documents.

“Lien” is a mortgage, deed of trust, levy, charge, pledge, security interest, or other encumbrance of any kind, whether voluntarily incurred or arising by operation of law or otherwise against any property.

“**Loan Documents**” are, collectively, this Agreement, the IP Security Agreement, each Secured Promissory Note, each Warrant, the Perfection Certificate(s), each Control Agreement, each Compliance Certificate, each Loan Payment Request Form, each Disbursement Letter, any subordination agreements, any note, or notes or guaranties executed by Borrower or any other Person, and any other present or future agreement entered into by Borrower, any Guarantor or any other Person for the benefit of the Lenders and Collateral Agent in connection with this Agreement; all as amended, restated, or otherwise modified or supplemented from time to time.

“**Loan Payment Request Form**” is that certain form attached hereto as EXHIBIT B-1.

“**Material Adverse Change**” is (a) a material adverse change in the business, operations or condition (financial or otherwise) of Borrower or any Subsidiary, when taken as a whole; (b) a material impairment of the prospect of repayment of any portion of the Obligations, or (c) a material adverse effect on the Collateral.

“**Material Agreement**” is any license, agreement or other contractual arrangement with a Person or Governmental Authority whereby Borrower or any of its Subsidiaries is reasonably likely to be required to transfer, either in-kind or in cash, prior to the Maturity Date, assets or property valued (book or market) at more than Five Thousand Dollars (\$500,000.00) in the aggregate or any license, agreement or other contractual arrangement conveying rights in or to any intellectual property necessary to make, use or sell any Inventory, products or services of Borrower or any Subsidiary.

“**Maturity Date**” is April 8, 2026.

“**Obligations**” are all of Borrower’s obligations to pay when due any debts, principal, interest, Lenders’ Expenses, the Prepayment Fee, the Final Fee, and other amounts Borrower owes the Lenders now or later, in connection with, related to, following, or arising from, out of or under, this Agreement or, the other Loan Documents (other than the Warrant), or otherwise, and including interest accruing after Insolvency Proceedings begin (whether or not allowed) and debts, liabilities, or obligations of Borrower assigned to the Lenders and/or Collateral Agent, and the performance of Borrower’s duties under the Loan Documents (other than the Warrant).

“**OFAC**” is the U.S. Department of Treasury Office of Foreign Assets Control.

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

“**Operating Documents**” are, for any Person, such Person’s formation documents, as certified by the Secretary of State (or equivalent agency) of such Person’s jurisdiction of organization on a date that is no earlier than thirty (30) days prior to the Effective Date, and, (a) if such Person is a corporation, its bylaws in current form, (b) if such Person is a limited liability company, its limited liability company agreement (or similar agreement), and (c) if such Person is a partnership, its partnership agreement (or similar agreement), each of the foregoing with all current amendments or modifications thereto.

“**Patents**” means all patents, patent applications and like protections including without limitation improvements, divisions, continuations, renewals, reissues, re-examination certificates, utility models, extensions and continuations-in-part of the same.

“**Payment Date**” is the first (1st) calendar day of each calendar month, commencing on May 1, 2021; provided, however, the Payment Date for April 2026 shall be the Maturity Date.

“**Permitted Indebtedness**” is:

- (a) Borrower’s Indebtedness to the Lenders and Collateral Agent under this Agreement and the other Loan Documents;
- (b) Indebtedness existing on the Effective Date and disclosed on the Perfection Certificate(s);
- (c) Subordinated Debt;
- (d) unsecured Indebtedness to trade creditors and Indebtedness in connection with credit cards incurred in the ordinary course of business;

(e) Indebtedness consisting of capitalized lease obligations and purchase money Indebtedness, in each case incurred by Borrower or any of its Subsidiaries to finance the acquisition, repair, improvement or construction of fixed or capital assets of such Person, provided that (i) the aggregate outstanding principal amount of all such Indebtedness does not exceed Two Hundred Fifty Thousand Dollars (\$250,000.00) at any time and (ii) the principal amount of such Indebtedness does not exceed the cost of the property so acquired or built or of such repairs or improvements financed with such Indebtedness (each measured at the time of such acquisition, repair, improvement or construction is made);

(f) Indebtedness incurred as a result of endorsing negotiable instruments received in the ordinary course of Borrower's business;

(g) extensions, refinancings, modifications, amendments and restatements of any items of Permitted Indebtedness (a) through (e) above, provided that the principal amount thereof is not increased or the terms thereof are not modified to impose materially more burdensome terms upon Borrower, or its Subsidiary, as the case may be;

(h) Indebtedness consisting of letters of credit, provided that the aggregate outstanding principal amount of all such Indebtedness does not exceed Two Hundred and Fifty Thousand Dollars (\$250,000.00) at any time;

(i) Indebtedness owed to current and former directors, officers and employees pursuant to deferred compensation, severance and retirement plans and similar obligations in the ordinary course of business; provided, however, the aggregate amount of such Indebtedness shall not exceed Five Hundred Thousand Dollars (\$500,000.00) at any time; and

(j) Indebtedness constituting Permitted Investments described in clause (i) of the definition of Permitted Investments.

"Permitted Investments" are:

(a) Investments disclosed on the Perfection Certificate(s) and existing on the Effective Date;

(b) Investments consisting of cash and Cash Equivalents, and (ii) any Investments permitted by Borrower's investment policy, as amended from time to time, provided that such investment policy (and any such amendment thereto) has been approved in writing by Collateral Agent;

(c) Investments consisting of the endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of Borrower;

(d) Investments consisting of Deposit Accounts in which Collateral Agent has a perfected security interest;

(e) Investments in connection with Transfers permitted by Section 7.1;

(f) Investments consisting of (i) travel advances and employee relocation loans and other employee loans and advances in the ordinary course of business, and (ii) loans to employees, officers or directors relating to the purchase of equity securities of Borrower or its Subsidiaries pursuant to employee stock purchase plans or agreements approved by Borrower's board of directors, not to exceed One Hundred Fifty Thousand Dollars (\$150,000.00) in the aggregate for (i) and (ii) in any fiscal year;

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

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

(i) Investments in Subsidiaries, not to exceed Two Hundred Fifty Thousand Dollars (\$250,000.00) per fiscal year; and

(j) non-cash Investments in joint ventures or strategic alliances in the ordinary course of Borrower's business consisting of the non exclusive licensing of technology, the development of technology or the providing of technical support.

"Permitted Licenses" are (A) licenses of over-the-counter software that is commercially available to the public and (B) non exclusive licenses for the use of the Intellectual Property of Borrower or any of its Subsidiaries entered into in the ordinary course of business, provided, that, with respect to each such license described in clause (B), the license constitutes an arms length transaction, the terms of which, on their face, do not provide for a sale or assignment of any Intellectual Property and do not restrict the ability of Borrower or any of its Subsidiaries, as applicable, to pledge, grant a security interest in or lien on, or assign or otherwise Transfer any Intellectual Property.

"Permitted Liens" are:

(a) Liens existing on the Effective Date and disclosed on the Perfection Certificates or arising under this Agreement and the other Loan Documents;

(b) Liens for taxes, fees, assessments or other government charges or levies, either (i) not due and payable or (ii) being contested in good faith and for which Borrower maintains adequate reserves on its Books, provided that no notice of any such Lien has been filed or recorded under the Internal Revenue Code of 1986, as amended, and the Treasury Regulations adopted thereunder;

(c) Liens securing Indebtedness permitted under clause (e) of the definition of "Permitted Indebtedness," provided that (i) such liens exist prior to the acquisition of, or attach substantially simultaneous with, or within twenty (20) days after the, acquisition, lease, repair, improvement or construction of, such property financed or leased by such Indebtedness and (ii) such liens do not extend to any property of Borrower other than the property (and proceeds thereof) acquired, leased or built, or the improvements or repairs, financed by such Indebtedness;

(d) Liens of landlords, carriers, warehousemen, suppliers, or other Persons that are possessory in nature arising in the ordinary course of business so long as such Liens attach only to Inventory, securing liabilities in the aggregate amount not to exceed One Hundred Fifty Thousand Dollars (\$150,000.00), and which are not delinquent or remain payable without penalty or which are being contested in good faith and by appropriate proceedings which proceedings have the effect of preventing the forfeiture or sale of the property subject thereto;

(e) Liens to secure payment of workers' compensation, employment insurance, old age pensions, social security and other like obligations incurred in the ordinary course of business (other than Liens imposed by ERISA);

(f) Liens incurred in the extension, renewal or refinancing of the indebtedness secured by Liens described in (a) through (c), but any extension, renewal or replacement Lien must be limited to the property encumbered by the existing Lien and the principal amount of the indebtedness may not increase;

(g) Easements, rights-of-way, restrictions, covenants, leases or subleases of real property granted in the ordinary course of Borrower's business (or, if referring to another Person, in the ordinary course of such Person's business), and leases, subleases, non exclusive licenses or sublicenses of personal property (other than Intellectual Property) granted in the ordinary course of Borrower's business (or, if referring to another Person, in the ordinary course of such Person's business) in each case not materially interfering with the ordinary conduct of the business of Borrower or such Person;

(h) banker's liens, rights of setoff and Liens in favor of financial institutions incurred in the ordinary course of business arising in connection with Borrower's deposit accounts or securities accounts held at such institutions solely to secure payment of fees and similar costs and expenses and provided such accounts are maintained in compliance with Section 6.6 hereof;

(i) Liens arising from judgments, decrees or attachments in circumstances not constituting an Event of Default under Section 8.4 or 8.7; and

(j) Permitted Licenses.

“**Person**” is any individual, sole proprietorship, partnership, limited liability company, joint venture, company, trust, unincorporated organization, association, corporation, institution, public benefit corporation, firm, joint stock company, estate, entity or government agency.

“**Prepayment Fee**” is, with respect to any Term Loan subject to prepayment prior to the Maturity Date, whether by mandatory or voluntary prepayment, acceleration or otherwise, an additional fee payable to the Lenders in amount equal to:

(i) for a prepayment made on or after the Effective Date through and including the first anniversary of the Effective Date, three percent (3.00%) of the principal amount (including any applicable payable in-kind amount) of the Term Loan prepaid; provided, however, a prepayment may only be made on or prior to the first anniversary of the Effective Date pursuant to Section 2.2(c) and no voluntary prepayment may be during such period;

(ii) for a prepayment made after the date which is the first anniversary of the Effective Date through and including the date which is the second anniversary of the Effective Date, two percent (2.00%) of the principal amount (including any applicable payable in-kind amount) of the Term Loan prepaid;

(iii) for a prepayment made after the date which is the second anniversary of the Effective Date through and including the date which is the third anniversary of the Effective Date, one percent (1.00%) of the principal amount (including any applicable payable in-kind amount) of the Term Loan prepaid; and

(iv) for a prepayment made after the date which is the third anniversary of the Effective Date and prior to the Maturity Date, zero percent (0.00%) of the principal amount (including any applicable payable in-kind amount) of the Term Loan prepaid.

“**Prime Rate**” means the Prime Rate published in the Money Rates section of the U.S. Edition of The Wall Street Journal.

“**Property**” means any interest in any kind of property or asset, whether real, personal or mixed, and whether tangible or intangible.

“**Pro Rata Share**” is, as of any date of determination, with respect to each Lender, a percentage (expressed as a decimal, rounded to the ninth decimal place) determined by dividing the outstanding principal amount of the Term Loan held by such Lender by the aggregate outstanding principal amount of the Term Loan.

“**Registered Organization**” is any “registered organization” as defined in the Code with such additions to such term as may hereafter be made under the Code.

“**Registration**” means any registration, authorization, approval, license, permit, clearance, certificate, and exemption issued or allowed by the FDA or state pharmacy licensing authorities (including, without limitation, new drug applications, abbreviated new drug applications, biologics license applications, investigational new drug applications, over-the-counter drug monograph, device pre-market approval applications, device pre-market notifications, investigational device exemptions, product recertifications, manufacturing approvals, registrations and authorizations, CE Marks, pricing and reimbursement approvals, labeling approvals or their foreign equivalent, controlled substance registrations, and wholesale distributor permits).

“**Regulatory Action**” means an administrative, regulatory, or judicial enforcement action, proceeding, investigation or inspection, FDA Form 483 notice of inspectional observation, warning letter, untitled letter, other notice of violation letter, recall, seizure, Section 305 notice or other similar written communication, injunction or consent decree, issued by the FDA or a federal or state court.

“**Related Persons**” means, with respect to any Person, each Affiliate of such Person and each director, officer, employee, agent, trustee, representative, attorney, accountant and each insurance, environmental, legal, financial and other advisor and other consultants and agents of or to such Person or any of its Affiliates.

“**Required Lenders**” means (i) for so long as all of the Persons that are Lenders on the Effective Date (each an “**Original Lender**”) have not assigned or transferred any of their interests in the Term Loan, Lenders holding one hundred percent (100%) of the aggregate outstanding principal balance of the Term Loan, or (ii) at any time from and after any Original Lender has assigned or transferred any interest in its Term Loan, Lenders holding at least fifty one percent (51%) of the aggregate outstanding principal balance of the Term Loan.

“Requirement of Law” is as to any Person, the organizational or governing documents of such Person, and any law (statutory or common), treaty, rule or regulation or determination of an arbitrator or a court or other Governmental Authority, in each case applicable to or binding upon such Person or any of its property or to which such Person or any of its property is subject.

“Responsible Officer” is any of the Chief Executive Officer or Chief Financial Officer of Borrower acting alone.

“Secured Promissory Note” is defined in Section 2.6.

“Secured Promissory Note Record” is a record maintained by each Lender with respect to the outstanding Obligations owed by Borrower to Lender and credits made thereto.

“Securities Account” is any “securities account” as defined in the Code with such additions to such term as may hereafter be made under the Code.

“Shares” is one hundred percent (100%) of the issued and outstanding capital stock, membership units or other securities owned or held of record by Borrower or Borrower’s Subsidiary, in any Subsidiary; provided that, in the event Borrower, demonstrates to Collateral Agent’s reasonable satisfaction, that a pledge of more than sixty five percent (65%) of the Shares of such Subsidiary which is a Foreign Subsidiary, creates a present and existing adverse tax consequence to Borrower under the U.S. Internal Revenue Code, “Shares” shall mean sixty-five percent (65%) of the issued and outstanding capital stock, membership units or other securities owned or held of record by Borrower or its Subsidiary in such Foreign Subsidiary.

“Solvent” is, with respect to any Person: the fair salable value of such Person’s consolidated assets (including goodwill minus disposition costs) exceeds the fair value of such Person’s liabilities; such Person is not left with unreasonably small capital after the transactions in this Agreement; and such Person is able to pay its debts (including trade debts) as they mature in the ordinary course (without taking into account any forbearance and extensions related thereto).

“Subordinated Debt” is indebtedness incurred by Borrower or any of its Subsidiaries subordinated to all Indebtedness of Borrower and/or its Subsidiaries to the Lenders (pursuant to a subordination, intercreditor, or other similar agreement in form and substance satisfactory to Collateral Agent and the Lenders entered into between Collateral Agent, Borrower, and/or any of its Subsidiaries, and the other creditor), on terms acceptable to Collateral Agent and the Lenders.

“Subsidiary” is, with respect to any Person, any Person of which more than fifty percent (50%) of the voting stock or other equity interests (in the case of Persons other than corporations) is owned or controlled, directly or indirectly, by such Person or through one or more intermediaries. Unless otherwise specified, references herein to a Subsidiary means a Subsidiary of Borrower.

“Term B Draw Period” is the period commencing on the later of June 30, 2021 and the first date on which Borrower achieves the Term B Milestone and ending on the earlier of (i) March 31, 2022 or (ii) the occurrence of an Event of Default (unless such Event of Default is waived by Collateral Agent and Lenders for the purposes of the continuation of the Term B Draw Period); provided, however, that the Term B Draw Period shall not commence if when Borrower achieves the Term B Milestone, an Event of Default has occurred and is continuing.

“Term B Milestone” is the achievement of Borrower, after the Effective Date, of (i) meeting the primary end points for either (A) FACT-1 clinical trial with Genentech, Inc. and National Surgical Adjuvant Breast and Bowel Project or (B) FACT-2 clinical trial with Puma Biotechnology, Inc. and West Cancer Center, (ii) receipt of unrestricted net cash proceeds of at least Fifty Million Dollars (\$50,000,000.00) from the sale and issuance of Borrower’s equity securities after the Effective Date, (iii) the ratio of aggregate amount of Indebtedness of Borrower to its then pro forma market capitalization equal to fifteen percent (15.00%) or less and (iv) compliance with its obligations under Section 6.12 (without taking into account any cure or remedy for a breach of such obligations) at all times through quarter ending immediately prior to the Funding Date of the Term B Loan.

“**Term C Milestone**” is the achievement of Borrower of (i) meeting the primary end points for either (A) commencement of a Phase 3 clinical trial with Genentech, Inc. or Puma Biotechnology, Inc., (ii) receipt of unrestricted net cash proceeds of at least Seventy Five Million Dollars (\$75,000,000.00) from the sale and issuance of Borrower’s equity securities after the Funding Date of Term B Loans, (iii) the ratio of aggregate amount of Indebtedness of Borrower to its then pro forma market capitalization equal to fifteen percent (15.00%) or less and (iv) compliance with its obligations under Section 6.12 (without taking into account any cure or remedy for a breach of such obligations) at all times through quarter ending immediately prior to the Funding Date of the Term C Loan.

“**Term C Draw Period**” is the period commencing on the later of January 1, 2022 and ending on the earlier of (i) March 31, 2023 and (ii) the occurrence of an Event of Default (unless such Event of Default is waived by Collateral Agent and Lenders for the purposes of the continuation of the Term C Draw Period).

“**Term Loan Commitment**” is, for any Lender, the obligation of such Lender to make the Term Loan, up to the principal amount shown on Schedule 1.1. “**Term Loan Commitments**” means the aggregate amount of such commitments of all Lenders.

“**Trademarks**” means any trademark and servicemark rights, whether registered or not, applications to register and registrations of the same and like protections, and the entire goodwill of the business of Borrower and each of its Subsidiaries connected with and symbolized by such trademarks.

“**TTM Revenue**” means trailing twelve (12) months’ revenue, determined in accordance with GAAP consistently applied, as of any date of determination.

“**Warrant**” means any of that certain Warrant to Purchase Stock dated the Effective Date issued by Borrower in favor of each Lender or such Lender’s Affiliates or any other warrant entered into in connection with the Term Loan, all as may be amended, restated, or otherwise modified or supplemented from time to time.

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IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the Effective Date.

BORROWER:

CELCUITY, INC.

By /s/ Brian F. Sullivan
Name: Brian F. Sullivan
Title: Chairman and Chief Executive Officer

COLLATERAL AGENT AND LENDER:

INNOVATUS LIFE SCIENCES LENDING FUND I, LP

By: Innovatus Life Sciences GP, LP
Its: General Partner

By /s/ Andrew Hobson
Name: Andrew Hobson
Title: Authorized Signatory

[Signature Page to Loan and Security Agreement]

SCHEDULE 1.1

Lenders and Commitments

Term A Loan

Lender	Term Loan A Commitment	Commitment Percentage
INNOVATUS LIFE SCIENCES LENDING FUND I, LP	\$15,000,000	100.00%
TOTAL	\$15,000,000	100.00%

Term B Loan

Lender	Term Loan B Commitment	Commitment Percentage
INNOVATUS LIFE SCIENCES LENDING FUND I, LP	\$5,000,000	100.00%
TOTAL	\$5,000,000	100.00%

Term C Loan

Lender	Term Loan B Commitment	Commitment Percentage
INNOVATUS LIFE SCIENCES LENDING FUND I, LP	\$5,000,000	100.00%
TOTAL	\$5,000,000	100.00%

EXHIBIT A

Description of Collateral

The Collateral consists of all of Borrower's right, title and interest in and to the following property:

All goods, Accounts (including health-care receivables), Equipment, Inventory, contract rights or rights to payment of money, leases, license agreements, franchise agreements, General Intangibles (including Intellectual Property), commercial tort claims, documents, instruments (including any promissory notes), chattel paper (whether tangible or electronic), cash, deposit accounts and other Collateral Accounts, all certificates of deposit, fixtures, letters of credit rights (whether or not the letter of credit is evidenced by a writing), securities, and all other investment property, supporting obligations, and financial assets, whether now owned or hereafter acquired, wherever located; and

All Borrower's Books relating to the foregoing, and any and all claims, rights and interests in any of the above and all substitutions for, additions, attachments, accessories, accessions and improvements to and replacements, products, proceeds and insurance proceeds of any or all of the foregoing.

EXHIBIT B-1

Loan Payment Request Form

[Intentionally Omitted]

EXHIBIT B-2

Form of Disbursement Letter

[Intentionally Omitted]

EXHIBIT C

Compliance Certificate

[Intentionally Omitted]

EXHIBIT D

Form of Secured Promissory Note

[see attached]

**SECURED PROMISSORY NOTE
(Term [A][B][C] Loan)**

\$ _____

Dated: [DATE]

FOR VALUE RECEIVED, the undersigned, CELCUITY, INC., a Delaware corporation (“**Borrower**”) HEREBY PROMISES TO PAY to the order of INNOVATUS LIFE SCIENCES LENDING FUND I, LP (“**Lender**”) the principal amount of [_____] MILLION DOLLARS (\$ _____) or such lesser amount as shall equal the outstanding principal balance of the Term [A][B][C] Loan made to Borrower by Lender, plus interest on the aggregate unpaid principal amount of such Term [A][B][C] Loan, at the rates and in accordance with the terms of the Loan and Security Agreement dated April 8, 2021 by and among Borrower, Lender, INNOVATUS LIFE SCIENCES LENDING FUND I, LP, as Collateral Agent, and the other Lenders from time to time party thereto (as amended, restated, supplemented or otherwise modified from time to time, the “**Loan Agreement**”). If not sooner paid, the entire principal amount and all accrued and unpaid interest hereunder shall be due and payable on the Maturity Date as set forth in the Loan Agreement. Any capitalized term not otherwise defined herein shall have the meaning attributed to such term in the Loan Agreement.

Principal, interest and all other amounts due with respect to the Term [A][B][C] Loan, are payable in lawful money of the United States of America to Lender as set forth in the Loan Agreement and this Secured Promissory Note (this “**Note**”). The principal amount of this Note and the interest rate applicable thereto, and all payments made with respect thereto, shall be recorded by Lender and, prior to any transfer hereof, endorsed on the grid attached hereto which is part of this Note.

The Loan Agreement, among other things, (a) provides for the making of a secured Term [A][B][C] Loan by Lender to Borrower, and (b) contains provisions for acceleration of the maturity hereof upon the happening of certain stated events.

This Note may not be prepaid except as set forth in Section 2.2 (c) and Section 2.2(d) of the Loan Agreement.

This Note and the obligation of Borrower to repay the unpaid principal amount of the Term [A][B][C] Loan, interest on the Term [A][B][C] Loan and all other amounts due Lender under the Loan Agreement is secured under the Loan Agreement.

Presentment for payment, demand, notice of protest and all other demands and notices of any kind in connection with the execution, delivery, performance and enforcement of this Note are hereby waived.

Borrower shall pay all reasonable fees and expenses, including, without limitation, reasonable and documented attorneys' fees and costs, incurred by Lender in the enforcement or attempt to enforce any of Borrower's obligations hereunder not performed when due.

This Note shall be governed by, and construed and interpreted in accordance with, the internal laws of the State of New York.

The ownership of an interest in this Note shall be registered on a record of ownership maintained by Lender or its agent. Notwithstanding anything else in this Note to the contrary, the right to the principal of, and stated interest on, this Note may be transferred only if the transfer is registered on such record of ownership and the transferee is identified as the owner of an interest in the obligation. Borrower shall be entitled to treat the registered holder of this Note (as recorded on such record of ownership) as the owner in fact thereof for all purposes and shall not be bound to recognize any equitable or other claim to or interest in this Note on the part of any other person or entity.

[Balance of Page Intentionally Left Blank]

IN WITNESS WHEREOF, Borrower has caused this Note to be duly executed by one of its officers thereunto duly authorized on the date hereof.

BORROWER:

CELCUITY, INC.

By _____

Name: _____

Title: _____

ANNEX I

Collateral Agent and Lender Terms

1. Appointment of Collateral Agent.

(a) Each Lender hereby appoints INNOVATUS LIFE SCIENCES LENDING FUND I, LP (together with any successor Collateral Agent pursuant to Section 7 of this Annex I) as Collateral Agent under the Loan Documents and authorizes Collateral Agent to (i) execute and deliver the Loan Documents and accept delivery thereof on its behalf from Borrower, (ii) take such action on its behalf and to exercise all rights, powers and remedies and perform the duties as are expressly delegated to Collateral Agent under such Loan Documents and (iii) exercise such powers as are reasonably incidental thereto.

(b) Without limiting the generality of clause (a) above, Collateral Agent shall have the sole and exclusive right and authority (to the exclusion of the Lenders), and is hereby authorized, to (i) act as the disbursing and collecting agent for the Lenders with

respect to all payments and collections arising in connection with the Loan Documents (including in any other bankruptcy, insolvency or similar proceeding), and each Person making any payment in connection with any Loan Document to any Lender is hereby authorized to make such payment to Collateral Agent, (ii) file and prove claims and file other documents necessary or desirable to allow the claims of Collateral Agent and Lenders with respect to any Obligation in any bankruptcy, insolvency or similar proceeding (but not to vote, consent or otherwise act on behalf of such Lender), (iii) act as collateral agent for Collateral Agent and each Lender for purposes of the perfection of all Liens created by the Loan Documents and all other purposes stated therein, (iv) manage, supervise and otherwise deal with the Collateral, (v) take such other action as is necessary or desirable to maintain the perfection and priority of the Liens created or purported to be created by the Loan Documents, (vi) except as may be otherwise specified in any Loan Document, exercise all remedies given to Collateral Agent and the other Lenders with respect to the Borrower and/or the Collateral, whether under the Loan Documents, applicable Requirements of Law or otherwise and (vii) execute any amendment, consent or waiver under the Loan Documents on behalf of any Lender that has consented in writing to such amendment, consent or waiver; provided, however, that Collateral Agent hereby appoints, authorizes and directs each Lender to act as collateral sub-agent for Collateral Agent and the Lenders for purposes of the perfection of all Liens with respect to the Collateral, including any Deposit Account maintained by Borrower with, and cash and Cash Equivalents held by, such Lender, and may further authorize and direct the Lenders to take further actions as collateral sub-agents for purposes of enforcing such Liens or otherwise to transfer the Collateral subject thereto to Collateral Agent, and each Lender hereby agrees to take such further actions to the extent, and only to the extent, so authorized and directed. Collateral Agent may, upon any term or condition it specifies, delegate or exercise any of its rights, powers and remedies under, and delegate or perform any of its duties or any other action with respect to, any Loan Document by or through any trustee, co-agent, employee, attorney-in-fact and any other Person (including any Lender). Any such Person shall benefit from this Annex I to the extent provided by Collateral Agent.

(c) Under the Loan Documents, Collateral Agent (i) is acting solely on behalf of the Lenders, with duties that are entirely administrative in nature, notwithstanding the use of the defined term “Collateral Agent”, the terms “agent”, “Collateral Agent” and “collateral agent” and similar terms in any Loan Document to refer to Collateral Agent, which terms are used for title purposes only, (ii) is not assuming any obligation under any Loan Document other than as expressly set forth therein or any role as agent, fiduciary or trustee of or for any Lender or any other Person and (iii) shall have no implied functions, responsibilities, duties, obligations or other liabilities under any Loan Document, and each Lender, by accepting the benefits of the Loan Documents, hereby waives and agrees not to assert any claim against Collateral Agent based on the roles, duties and legal relationships expressly disclaimed in clauses (i) through (iii) above. Except as expressly set forth in the Loan Documents, Collateral Agent shall not have any duty to disclose, and shall not be liable for failure to disclose, any information relating to Borrower or any of its Subsidiaries that is communicated to or obtained by [LENDER 2] or any of its Affiliates in any capacity.

2. Binding Effect; Use of Discretion; E-Systems.

(a) Each Lender, by accepting the benefits of the Loan Documents, agrees that (i) any action taken by Collateral Agent or Required Lenders (or, if expressly required in any Loan Document, a greater proportion of the Lenders) in accordance with the provisions of the Loan Documents, (ii) any action taken by Collateral Agent in reliance upon the instructions of Required Lenders (or, where so required, such greater proportion) and (iii) the exercise by Collateral Agent or Required Lenders (or, where so required, such greater proportion) of the powers set forth herein or therein, together with such other powers as are reasonably incidental thereto, shall be authorized and binding upon all of Lenders.

(b) If Collateral Agent shall request instructions from Required Lenders or all affected Lenders with respect to any act or action (including failure to act) in connection with any Loan Document, then Collateral Agent shall be entitled to refrain from such act or taking such action unless and until Collateral Agent shall have received instructions from Required Lenders or all affected Lenders, as the case may be, and Collateral Agent shall not incur liability to any Person by reason of so refraining. Collateral Agent shall be fully justified in failing or refusing to take any action under any Loan Document (i) if such action would, in the opinion of Collateral Agent, be contrary to any Requirement of Law or any Loan Document, (ii) if such action would, in the opinion of Collateral Agent, expose Collateral Agent to any potential liability under any Requirement of Law or (iii) if Collateral Agent shall not first be indemnified to its satisfaction against any and all liability and expense which may be incurred by it by reason of taking or continuing to take any such action. Without limiting the foregoing, no Lender shall have any right of action whatsoever against Collateral Agent as a result of Collateral Agent acting or refraining from acting under any Loan Document in accordance with the instructions of Required Lenders or all affected Lenders, as applicable.

(c) Collateral Agent is hereby authorized by Borrower and each Lender to establish procedures (and to amend such procedures from time to time) to facilitate administration and servicing of the Term Loan and other matters incidental thereto. Without

limiting the generality of the foregoing, Collateral Agent is hereby authorized to establish procedures to make available or deliver, or to accept, notices, documents (including, without limitation, borrowing base certificates) and similar items on, by posting to or submitting and/or completion, on E-Systems. Borrower and each Lender acknowledges and agrees that the use of transmissions via an E-System or electronic mail is not necessarily secure and that there are risks associated with such use, including risks of interception, disclosure and abuse, and Borrower and each Lender assumes and accepts such risks by hereby authorizing the transmission via E-Systems or electronic mail. Each “e-signature” on any such posting shall be deemed sufficient to satisfy any requirement for a “signature”, and each such posting shall be deemed sufficient to satisfy any requirement for a “writing”, in each case including pursuant to any Loan Document, any applicable provision of any Code, the federal Uniform Electronic Transactions Act, the Electronic Signatures in Global and National Commerce Act and any substantive or procedural Requirement of Law governing such subject matter. All uses of an E-System shall be governed by and subject to, in addition to this Section, the separate terms, conditions and privacy policy posted or referenced in such E-System (or such terms, conditions and privacy policy as may be updated from time to time, including on such E-System) and related contractual obligations executed by Collateral Agent, Borrower and/or Lenders in connection with the use of such E-System. ALL E-SYSTEMS AND ELECTRONIC TRANSMISSIONS SHALL BE PROVIDED “AS IS” AND “AS AVAILABLE”. NO REPRESENTATION OR WARRANTY OF ANY KIND IS MADE BY AGENT, ANY LENDER OR ANY OF THEIR RELATED PERSONS IN CONNECTION WITH ANY E-SYSTEMS.

3. Collateral Agent’s Reliance, Etc. Collateral Agent may, without incurring any liability hereunder, (a) consult with any of its Related Persons and, whether or not selected by it, any other advisors, accountants and other experts (including advisors to, and accountants and experts engaged by, Borrower) and (b) rely and act upon any document and information (including those transmitted by electronic transmission) and any telephone message or conversation, in each case believed by it to be genuine and transmitted, signed or otherwise authenticated by the appropriate parties. None of Collateral Agent and its Related Persons shall be liable for any action taken or omitted to be taken by any of them under or in connection with any Loan Document, and each Lender and Borrower hereby waives and shall not assert (and Borrower shall cause its Subsidiaries to waive and agree not to assert) any right, claim or cause of action based thereon, except to the extent of liabilities resulting from the gross negligence or willful misconduct of Collateral Agent or, as the case may be, such Related Person (each as determined in a final, non-appealable judgment of a court of competent jurisdiction) in connection with the duties of Collateral Agent expressly set forth herein. Without limiting the foregoing, Collateral Agent: (i) shall not be responsible or otherwise incur liability for any action or omission taken in reliance upon the instructions of the Required Lenders or for the actions or omissions of any of its Related Persons, except to the extent that a court of competent jurisdiction determines in a final non-appealable judgment that Collateral Agent acted with gross negligence or willful misconduct in the selection of such Related Person; (ii) shall not be responsible to any Lender or other Person for the due execution, legality, validity, enforceability, effectiveness, genuineness, sufficiency or value of, or the attachment, perfection or priority of any Lien created or purported to be created under or in connection with, any Loan Document; (iii) makes no warranty or representation, and shall not be responsible, to any Lender or other Person for any statement, document, information, representation or warranty made or furnished by or on behalf of Borrower or any Related Person of Borrower in connection with any Loan Document or any transaction contemplated therein or any other document or information with respect to Borrower, whether or not transmitted or (except for documents expressly required under any Loan Document to be transmitted to the Lenders) omitted to be transmitted by Collateral Agent, including as to completeness, accuracy, scope or adequacy thereof, or for the scope, nature or results of any due diligence performed by Collateral Agent in connection with the Loan Documents; and (iv) shall not have any duty to ascertain or to inquire as to the performance or observance of any provision of any Loan Document, whether any condition set forth in any Loan Document is satisfied or waived, as to the financial condition of Borrower or as to the existence or continuation or possible occurrence or continuation of any Event of Default, and shall not be deemed to have notice or Knowledge of such occurrence or continuation unless it has received a notice from Borrower or any Lender describing such Event of Default that is clearly labeled “notice of default” (in which case Collateral Agent shall promptly give notice of such receipt to all Lenders, provided that Collateral Agent shall not be liable to any Lender for any failure to do so, except to the extent that such failure is attributable to Collateral Agent’s gross negligence or willful misconduct as determined by a final non-appealable judgment of a court of competent jurisdiction); and, for each of the items set forth in clauses (i) through (iv) above, each Lender and Borrower hereby waives and agrees not to assert (and Borrower shall cause its Subsidiaries to waive and agree not to assert) any right, claim or cause of action it might have against Collateral Agent based thereon.

4. Collateral Agent Individually. Collateral Agent and its Affiliates may make loans and other extensions of credit to, acquire stock and stock equivalents of, engage in any kind of business with, Borrower or any Affiliate of Borrower as though it were not acting as Collateral Agent and may receive separate fees and other payments therefor. To the extent Collateral Agent or any of its Affiliates makes the Term Loan or otherwise becomes a Lender hereunder, it shall have and may exercise the same rights and powers hereunder and shall be subject to the same obligations and liabilities as any other Lender and the terms “Lender”, “Required Lender” and any similar terms

shall, except where otherwise expressly provided in any Loan Document, include, without limitation, Collateral Agent or such Affiliate, as the case may be, in its individual capacity as Lender, or as one of the Required Lenders.

5. Lender Credit Decision; Collateral Agent Report. Each Lender acknowledges that it shall, independently and without reliance upon Collateral Agent, any Lender or any of their Related Persons or upon any document solely or in part because such document was transmitted by Collateral Agent or any of its Related Persons, conduct its own independent investigation of the financial condition and affairs of Borrower and make and continue to make its own credit decisions in connection with entering into, and taking or not taking any action under, any Loan Document or with respect to any transaction contemplated in any Loan Document, in each case based on such documents and information as it shall deem appropriate. Except for documents expressly required by any Loan Document to be transmitted by Collateral Agent to the Lenders, Collateral Agent shall not have any duty or responsibility to provide any Lender with any credit or other information concerning the business, prospects, operations, Property, financial and other condition or creditworthiness of Borrower or any Affiliate of Borrower that may come in to the possession of Collateral Agent or any of its Related Persons. Each Lender agrees that it shall not rely on any field examination, audit or other report provided by Collateral Agent or its Related Persons (a “**Collateral Agent Report**”). Each Lender further acknowledges that any Collateral Agent Report (a) is provided to the Lenders solely as a courtesy, without consideration, and based upon the understanding that such Lender will not rely on such Collateral Agent Report, (b) was prepared by Collateral Agent or its Related Persons based upon information provided by Borrower solely for Collateral Agent’s own internal use, and (c) may not be complete and may not reflect all information and findings obtained by Collateral Agent or its Related Persons regarding the operations and condition of Borrower. Neither Collateral Agent nor any of its Related Persons makes any representations or warranties of any kind with respect to (i) any existing or proposed financing, (ii) the accuracy or completeness of the information contained in any Collateral Agent Report or in any related documentation, (iii) the scope or adequacy of Collateral Agent’s and its Related Persons’ due diligence, or the presence or absence of any errors or omissions contained in any Collateral Agent Report or in any related documentation, and (iv) any work performed by Collateral Agent or Collateral Agent’s Related Persons in connection with or using any Collateral Agent Report or any related documentation. Neither Collateral Agent nor any of its Related Persons shall have any duties or obligations in connection with or as a result of any Lender receiving a copy of any Collateral Agent Report. Without limiting the generality of the foregoing, neither Collateral Agent nor any of its Related Persons shall have any responsibility for the accuracy or completeness of any Collateral Agent Report, or the appropriateness of any Collateral Agent Report for any Lender’s purposes, and shall have no duty or responsibility to correct or update any Collateral Agent Report or disclose to any Lender any other information not embodied in any Collateral Agent Report, including any supplemental information obtained after the date of any Collateral Agent Report. Each Lender releases, and agrees that it will not assert, any claim against Collateral Agent or its Related Persons that in any way relates to any Collateral Agent Report or arises out of any Lender having access to any Collateral Agent Report or any discussion of its contents, and agrees to indemnify and hold harmless Collateral Agent and its Related Persons from all claims, liabilities and expenses relating to a breach by any Lender arising out of such Lender’s access to any Collateral Agent Report or any discussion of its contents.

6. Indemnification. Each Lender agrees to reimburse Collateral Agent and each of its Related Persons (to the extent not reimbursed by Borrower as required under the Loan Documents) promptly upon demand for its Pro Rata Share of any out-of-pocket costs and expenses (including, without limitation, fees, charges and disbursements of financial, legal and other advisors and any taxes or insurance paid in the name of, or on behalf of, Borrower) incurred by Collateral Agent or any of its Related Persons in connection with the preparation, syndication, execution, delivery, administration, modification, amendment, consent, waiver or enforcement of, or the taking of any other action (whether through negotiations, through any work-out, bankruptcy, restructuring or other legal or other proceeding (including, without limitation, preparation for and/or response to any subpoena or request for document production relating thereto) or otherwise) in respect of, or legal advice with respect to, its rights or responsibilities under, any Loan Document. Each Lender further agrees to indemnify Collateral Agent and each of its Related Persons (to the extent not reimbursed by Borrower as required under the Loan Documents), ratably according to its Pro Rata Share, from and against any and all liabilities, obligations, losses, damages, penalties, actions, judgments, suits, costs, expenses or disbursements of any kind or nature whatsoever (including, to the extent not indemnified by the applicable Lender, taxes, interests and penalties imposed for not properly withholding or backup withholding on payments made to or for the account of any Lender) that may be imposed on, incurred by, or asserted against Collateral Agent or any of its Related Persons in any matter relating to or arising out of, in connection with or as a result of any Loan Document or any other act, event or transaction related, contemplated in or attendant to any such document, or, in each case, any action taken or omitted to be taken by Collateral Agent or any of its Related Persons under or with respect to the foregoing; provided that no Lender shall be liable to Collateral Agent or any of its Related Persons under this Section 6 of this Annex I to the extent such liability has resulted from the gross negligence or willful misconduct of Collateral Agent or, as the case may be, such Related Person, as determined by a final non-appealable judgment of a court of competent jurisdiction. To the extent required by any applicable Requirement of Law, Collateral Agent may withhold from any payment to any Lender under a Loan Document an amount equal to any applicable withholding tax. If the Internal Revenue Service or any other Governmental Authority asserts a claim that Collateral Agent did not properly withhold tax from amounts paid to or for the account

of any Lender for any reason, or if Collateral Agent reasonably determines that it was required to withhold taxes from a prior payment to or for the account of any Lender but failed to do so, such Lender shall promptly indemnify Collateral Agent fully for all amounts paid, directly or indirectly, by Collateral Agent as tax or otherwise, including penalties and interest, and together with all expenses incurred by Collateral Agent. Collateral Agent may offset against any payment to any Lender under a Loan Document, any applicable withholding tax that was required to be withheld from any prior payment to such Lender but which was not so withheld, as well as any other amounts for which Collateral Agent is entitled to indemnification from such Lender under the immediately preceding sentence of this Section 6 of this Annex I.

7. Successor Collateral Agent. Collateral Agent may resign at any time by delivering notice of such resignation to the Lenders and Borrower, effective on the date set forth in such notice or, if no such date is set forth therein, upon the date such notice shall be effective, in accordance with the terms of this Section 7 of this Annex I. If Collateral Agent delivers any such notice, the Required Lenders shall have the right to appoint a successor Collateral Agent. If, after 30 days after the date of the retiring Collateral Agent's notice of resignation, no successor Collateral Agent has been appointed by the Required Lenders that has accepted such appointment, then the retiring Collateral Agent may, on behalf of the Lenders, appoint a successor Collateral Agent from among the Lenders. Effective immediately upon its resignation, (a) the retiring Collateral Agent shall be discharged from its duties and obligations under the Loan Documents, (b) the Lenders shall assume and perform all of the duties of Collateral Agent until a successor Collateral Agent shall have accepted a valid appointment hereunder, (c) the retiring Collateral Agent and its Related Persons shall no longer have the benefit of any provision of any Loan Document other than with respect to any actions taken or omitted to be taken while such retiring Collateral Agent was, or because such Collateral Agent had been, validly acting as Collateral Agent under the Loan Documents, and (iv) subject to its rights under Section 2(b) of this Annex I, the retiring Collateral Agent shall take such action as may be reasonably necessary to assign to the successor Collateral Agent its rights as Collateral Agent under the Loan Documents. Effective immediately upon its acceptance of a valid appointment as Collateral Agent, a successor Collateral Agent shall succeed to, and become vested with, all the rights, powers, privileges and duties of the retiring Collateral Agent under the Loan Documents.

8. Release of Collateral. Each Lender hereby consents to the release and hereby directs Collateral Agent to release (or in the case of clause (b)(ii) below, release or subordinate) the following:

(a) any Guarantor or Subsidiary "co-Borrower" if all of the stock of such Subsidiary owned by Borrower is sold or transferred in a transaction permitted under the Loan Documents (including pursuant to a valid waiver or consent), to the extent that, after giving effect to such transaction, such Subsidiary would not be required to guaranty any Obligations pursuant to any Loan Document; and

(b) any Lien held by Collateral Agent for the benefit of itself and the Lenders against (i) any Collateral that is sold or otherwise disposed of by Borrower in a transaction permitted by the Loan Documents (including pursuant to a valid waiver or consent), (ii) any Collateral subject to a Lien that is expressly permitted under clause (c) of the definition of the term "Permitted Lien" and (iii) all of the Collateral and Borrower, upon (A) termination of all of the Commitments, (B) payment in full in cash of all of the Obligations that Collateral Agent has theretofore been notified in writing by the holder of such Obligation are then due and payable, and (C) to the extent requested by Collateral Agent, receipt by Collateral Agent and Lenders of liability releases from Borrower in form and substance acceptable to Collateral Agent (the satisfaction of the conditions in this clause (iii), the "**Termination Date**").

9. Setoff and Sharing of Payments. In addition to any rights now or hereafter granted under any applicable requirement of law and not by way of limitation of any such rights, upon the occurrence and during the continuance of any Event of Default and subject to Section 10(d) of this Annex I, each Lender is hereby authorized at any time or from time to time upon the direction of Collateral Agent, without notice to Borrower or any other Person, any such notice being hereby expressly waived, to setoff and to appropriate and to apply any and all balances held by it at any of its offices for the account of Borrower (regardless of whether such balances are then due to Borrower) and any other properties or assets at any time held or owing by that Lender or that holder to or for the credit or for the account of Borrower against and on account of any of the Obligations that are not paid when due. Any Lender exercising a right of setoff or otherwise receiving any payment on account of the Obligations in excess of its Pro Rata Share thereof shall purchase for cash (and the other Lenders or holders shall sell) such participations in each such other Lender's or holder's Pro Rata Share of the Obligations as would be necessary to cause such Lender to share the amount so offset or otherwise received with each other Lender or holder in accordance with their respective Pro Rata Shares of the Obligations. Borrower agrees, to the fullest extent permitted by law, that (a) any Lender may exercise its right to offset with respect to amounts in excess of its Pro Rata Share of the Obligations and may purchase participations in accordance with the preceding sentence and (b) any Lender so purchasing a participation in the Term Loan made or other Obligations held by other Lenders or holders may exercise all rights of offset, bankers' lien, counterclaim or similar rights with respect to

such participation as fully as if such Lender or holder were a direct holder of the Term Loan and the other Obligations in the amount of such participation. Notwithstanding the foregoing, if all or any portion of the offset amount or payment otherwise received is thereafter recovered from the Lender that has exercised the right of offset, the purchase of participations by that Lender shall be rescinded and the purchase price restored without interest.

10. **Advances; Payments; Non-Funding Lenders; Actions in Concert.**

(a) Advances; Payments. If Collateral Agent receives any payment with respect to the Term Loan for the account of Lenders on or prior to 2:00 p.m. (New York time) on any Business Day, Collateral Agent shall pay to each applicable Lender such Lender's Pro Rata Share of such payment on such Business Day. If Collateral Agent receives any payment with respect to the Term Loan for the account of Lenders after 2:00 p.m. (New York time) on any Business Day, Collateral Agent shall pay to each applicable Lender such Lender's Pro Rata Share of such payment on the next Business Day.

(b) Return of Payments.

(i) If Collateral Agent pays an amount to a Lender under this Agreement in the belief or expectation that a related payment has been or will be received by Collateral Agent from Borrower and such related payment is not received by Collateral Agent, then Collateral Agent will be entitled to recover such amount (including interest accruing on such amount at the rate otherwise applicable to such Obligation) from such Lender on demand without setoff, counterclaim or deduction of any kind.

(ii) If Collateral Agent determines at any time that any amount received by Collateral Agent under any Loan Document must be returned to Borrower or paid to any other Person pursuant to any insolvency law or otherwise, then, notwithstanding any other term or condition of any Loan Document, Collateral Agent will not be required to distribute any portion thereof to any Lender. In addition, each Lender will repay to Collateral Agent on demand any portion of such amount that Collateral Agent has distributed to such Lender, together with interest at such rate, if any, as Collateral Agent is required to pay to Borrower or such other Person, without setoff, counterclaim or deduction of any kind and Collateral Agent will be entitled to set off against future distributions to such Lender any such amounts (with interest) that are not repaid on demand.

(c) Non-Funding Lenders.

(i) Unless Collateral Agent shall have received notice from a Lender prior to the date of any Term Loan that such Lender will not make available to Collateral Agent such Lender's Pro Rata Share of such Term Loan, Collateral Agent may assume that such Lender will make such amount available to it on the date of such Term Loan in accordance with Section 2(b) of this Annex I, and Collateral Agent may (but shall not be obligated to), in reliance upon such assumption, make available a corresponding amount for the account of Borrower on such date. If and to the extent that such Lender shall not have made such amount available to Collateral Agent, such Lender and Borrower severally agree to repay to Collateral Agent forthwith on demand such corresponding amount together with interest thereon, for each day from the day such amount is made available to Borrower until the day such amount is repaid to Collateral Agent, at a rate per annum equal to the interest rate applicable to the Obligation that would have been created when Collateral Agent made available such amount to Borrower had such Lender made a corresponding payment available. If such Lender shall repay such corresponding amount to Collateral Agent, the amount so repaid shall constitute such Lender's portion of such Term Loan for purposes of this Agreement.

(ii) To the extent that any Lender has failed to fund any Term Loan or any other payments required to be made by it under the Loan Documents after any such Term Loan is required to be made or such payment is due (a "**Non-Funding Lender**"), Collateral Agent shall be entitled to set off the funding short-fall against that Non-Funding Lender's Pro Rata Share of all payments received from Borrower. The failure of any Non-Funding Lender to make any Term Loan or any payment required by it hereunder shall not relieve any other Lender (each such other Lender, an "**Other Lender**") of its obligations to make such Term Loan, but neither any Other Lender nor Collateral Agent shall be responsible for the failure of any Non-Funding Lender to make such Term Loan or make any other payment required hereunder. Notwithstanding anything set forth herein to the contrary, a Non-Funding Lender shall not have any voting or consent rights under or with respect to any Loan Document or constitute a "Lender" (or be included in the calculation of "Required Lender" hereunder) for any voting or consent rights under or with respect to any Loan Document. At Borrower's request, Collateral Agent or a Person reasonably acceptable to Collateral Agent shall have the right with Collateral Agent's consent and in Collateral Agent's sole discretion (but Collateral Agent or any such Person shall have no obligation) to purchase from any Non-Funding Lender, and each Lender agrees that if it becomes a Non-Funding Lender it shall, at Collateral Agent's request, sell and assign

to Collateral Agent or such Person, all of the Term Loan Commitment (if any), and all of the outstanding Term Loan of that Non-Funding Lender for an amount equal to the aggregate outstanding principal balance of the Term Loan held by such Non-Funding Lender and all accrued interest with respect thereto through the date of sale, such purchase and sale to be consummated pursuant to an executed assignment agreement in form and substance reasonably satisfactory to, and acknowledged by, Collateral Agent.

(d) Actions in Concert. Anything in this Agreement to the contrary notwithstanding, each Lender hereby agrees with each other Lender that no Lender shall take any action to protect or enforce its rights arising out of any Loan Document (including exercising any rights of setoff) without first obtaining the prior written consent of Collateral Agent or Required Lenders, it being the intent of Lenders that any such action to protect or enforce rights under any Loan Document shall be taken in concert and at the direction or with the consent of Collateral Agent or Required Lenders.

ANNEX Y

LOAN INTEREST RATE AND PAYMENT OF PRINCIPAL
(Term Loan)

[Intentionally Omitted]

Certain information where indicated below in brackets has been excluded from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed

LICENSE AGREEMENT

THIS LICENSE AGREEMENT (“**Agreement**”) is made effective as of the 8th day of April, 2021 (the “**Effective Date**”), by and between Celcuity Inc., a corporation organized and existing under the laws of Delaware with offices at 16305 36th Avenue North, Suite 100 Minneapolis, MN 55446 (“**Licensee**”) and Pfizer Inc, a corporation organized and existing under the laws of Delaware with offices at 235 East 42nd Street, New York, New York 10017 (“**Pfizer**”). Licensee and Pfizer may, from time-to-time, be individually referred to as a “**Party**” and collectively referred to as the “**Parties**”.

RECITALS

WHEREAS, Pfizer Controls the Licensed Technology (hereinafter defined); and

WHEREAS, Licensee wishes to obtain, and Pfizer wishes to grant, certain licenses under the Licensed Technology on the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the mutual agreements and covenants set forth herein and other good and valuable consideration, the receipt and sufficiency of which the Parties hereby acknowledge, the Parties, intending to be legally bound hereby, agree to the foregoing and as follows:

1. DEFINITIONS.

Unless specifically set forth to the contrary herein, the following terms and phrases, whether used in the singular or plural, including any grammatical conjugates thereof, have the respective meanings set forth below:

- 1.1. “**Affiliate**” means, with respect to a Party, any Person that, on the Effective Date or during the Term, controls, is controlled by, or is under common control with that Party. For the purpose of this definition, “**control**” shall refer to: (a) the possession, directly or indirectly, of the power to direct or cause the direction of the management or policies of an entity, whether through the ownership of voting securities or other ownership interest, by contract or otherwise, or (b) the ownership, directly or indirectly, of [***] or more of the voting securities or other ownership interest of such entity.
- 1.2. “**Agreement**” is defined in the introduction to this Agreement.
- 1.3. “**Applicable Law**” means any applicable law, statute, rule, regulation, order, judgment or ordinance of any Governmental Authority.
- 1.4. “**Bankruptcy Code**” is defined in Section 13.3.
- 1.5. “**Bankruptcy Event**” is defined in Section 13.3.

- 1.6. “**Business Day**” means any day other than a Saturday, a Sunday or a day on which commercial banks located in New York, New York are authorized or required by Applicable Law to remain closed.
- 1.7. “**Calendar Quarter**” means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.
- 1.8. “**Calendar Year**” means each calendar year.
- 1.9. “**Cap**” is defined in Section 12.2.

1.10. “CDA” is defined in Section 17.11.1.

1.11. “**Change of Control**” means, with respect to a Party, whether effected in a single transaction or a series of related transactions, (a) the acquisition of beneficial ownership, directly or indirectly, by any Person (other than such Party or an Affiliate of such Party) of securities or other voting interest of such Party representing a majority or more of the combined voting power of such Party’s then-outstanding securities or other voting interests; (b) any merger, reorganization, consolidation, share exchange, business combination or similar transaction involving such Party (i) pursuant to which more than [***] of the outstanding voting securities of such Party (or, if applicable, the ultimate parent of such Party) would be converted into cash or securities of any other Person or (ii) that results in the holders of beneficial ownership of the voting securities or other voting interests of such Party (or, if applicable, the ultimate parent of such Party) immediately prior to such merger, reorganization, consolidation or business combination ceasing to hold beneficial ownership of [***] of the combined voting power of the surviving entity immediately after such merger, reorganization, consolidation, share exchange, business combination or similar transaction; (c) any sale, lease, exchange, contribution or other transfer of all or substantially all of the assets of such Party and its subsidiaries taken as a whole, other than the sale or disposition of such assets to an Affiliate of such Party; (d) any sale, lease, exchange, contribution or other transfer of (other than granting of a license or sublicense) all or substantially all of the assets to which this Agreement relates, except the sale or disposition of such assets to an Affiliate of such Party; or (e) the approval of any plan or proposal for the liquidation or dissolution of such Party that does not otherwise fall under any of foregoing clauses (a) through (d).

1.12. “**Claims**” is defined in Section 11.1.

1.13. “**Clinical Trial**” means any of a Phase I Clinical Trial, a Phase II Clinical Trial or a Phase III Clinical Trial.

1.14. “**CMO**” means a contract manufacturing organization.

1.15. “**Combination Product**” means a product that includes or incorporates the Compound or any Product in combination with one (1) or more Other Active Ingredients (as defined in the definition of Net Sales), whether the Compound or Product(s), on the one hand, and such Other Active Ingredients, on the other hand, are formulated or packaged together.

1.16. “**Commercialize**” or “**Commercialization**” means to market, promote, distribute, offer for sale, sell, import, have imported, export, have exported or otherwise commercialize a compound or product. When used as a noun, “**Commercialization**” means any and all activities involved in Commercializing.

1.17. “**Commercially Reasonable Efforts**” means, with respect to the Development or Commercialization of a Product, that level of efforts and resources commonly dedicated by a similarly situated company in the research-based pharmaceutical industry to the development or commercialization, as the case may be, of a product of similar commercial potential at a similar stage in its lifecycle, in each case taking into account issues of safety and efficacy, product profile, the proprietary position, the then-current competitive environment for such product and the likely timing of such products entry into the market, the regulatory environment and the status of such product, reimbursement and pricing environment, and other relevant scientific, technical and commercial factors.

1.18. “**Compliance Laws**” is defined in Section 10.4.

1.19. “**Compound**” means each of the compounds set forth on Schedule 1.19 hereto, in each case, in all dosage forms, formulations, presentations, line extensions and package configurations and any and all [***].

1.20. “**Confidential Information**” is defined in Section 9.1.

1.21. “**Control**” or “**Controlled**” means, with respect to any Intellectual Property Rights or other rights to provide data or other information, the legal authority or right (whether by ownership, license (other than any license granted pursuant to this Agreement) or otherwise) of a Party or any of its Affiliates to grant a license or a sublicense of or under such Intellectual Property Rights to the other Party or provide such data or other information to such other Party, in each case without breaching the terms of any agreement with a Third Party.

1.22. “**CRO**” means a contract research organization.

1.23. “**Develop**” or “**Development**” means to conduct any and all research or development activities necessary to obtain Regulatory Approval.

1.24. “**Developed IP**” means any Intellectual Property Rights that are: (a) related to Compound or Product, (b) conceived or reduced to practice by Licensee, its Affiliates or sublicensees alone or together with one or more Third Parties during the Term and (c) actually used by Licensee, its Affiliates or sublicensees in the Development, Manufacture or Commercialization of the Compound or Product.

1.25. “**Development Plan**” is defined in Section 4.7.

1.26. “[***] **Milestone**” is defined in Section 5.3.

1.27. “[***] **Milestone Payment Plan**” is defined in Section 5.3.

1.28. “**Disputes**” is defined in Section 16.1.

1.29. “**Effective Date**” is defined in the introduction to this Agreement.

1.30. “**Election Notice**” is defined in Section 7.2.3.

1.31. “**FDA**” means the United States Food and Drug Administration, or a successor federal agency thereto.

1.32. “**Fees**” is defined in Section 12.2.

1.33. “**Field**” means the treatment, prevention, diagnosis, control, cure, mitigation or maintenance of all diseases or disorders in humans.

1.34. “**First Commercial Sale**” means the first sale of the Product by Licensee or Licensee’s Affiliate or sublicensee to a Third Party in a country in the Territory following receipt of Regulatory Approval for such Product in such country.

1.35. “**Force Majeure Event**” is defined in Section 17.4.

1.36. “**GAAP**” means United States generally accepted accounting principles or an alternative international generally accepted standard of accounting principles used by Licensee, including International Reporting Financial Standards, in each case consistently applied.

1.37. “**Generic Competition**” means, with respect to a particular country in the Territory, when the Generic Products have, in the aggregate during a particular Calendar Quarter, achieved more than [***] of the market share in such country by unit volume of combined unit sales of the relevant Product and all Generic Products.

1.38. “**Generic Product**” means, with respect to a particular country in the Territory, any pharmaceutical product that (a) is marketed for sale by a Third Party not authorized by Licensee, (b) receives Regulatory Approval (with or without pricing or reimbursement approval) in such country in full or partial reliance on the Regulatory Approval (but not necessarily pricing or reimbursement approval) of a Product, and (c) is determined by a Regulatory Authority to be therapeutically equivalent to and substitutable with the Product, it being acknowledged that the foregoing standard is intended to be generally consistent with the standard set forth in the introduction to the “Orange Book,” as amended from time to time, or any analogous or comparable standard in any country outside of the United States. For avoidance of doubt, in the United States, a “Generic Product” as defined herein includes one approved under Section 505(j) of the FD&C Act, as supplemented or amended.

- 1.39. “Good Manufacturing Practice” or “GMP”** means the regulatory requirements for current good manufacturing practices for pharmaceuticals promulgated by the FDA, as the same may be amended from time to time, and such standards of good manufacturing practice as are required by the Regulatory Authorities of the EU and other organizations and Governmental Authorities in countries in which any Product is intended to be manufactured or sold, to the extent such standards are not less stringent than United States GMP; *provided* that a Party shall not be held to any standards required by countries outside the United States and EU unless such standards have been specifically identified and approved for implementation by the mutual written agreement of the Parties.
- 1.40. “Government Official”** is defined in Section 10.4.
- 1.41. “Governmental Authority”** means any United States federal, state or local organization or authority, or any foreign government or any 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, or any court or tribunal (or any department, bureau or division thereof), or any governmental arbitrator or arbitral body. For clarity, any Regulatory Authority shall be a Governmental Authority.
- 1.42. “IND”** means: (a) an investigational new drug application filed with the FDA for authorization for the investigation of any Product, and (b) any of its foreign equivalents as filed with the applicable Regulatory Authorities in other countries or regulatory jurisdictions in the Territory, as applicable.
- 1.43. “Indication”** means a separate and distinct disease or medical condition.
- 1.44. “Intellectual Property Rights”** means all trade secrets, copyrights, Patent Rights, trademarks, moral rights, Know-How and any and all other intellectual property or proprietary rights now known or hereafter recognized in any jurisdiction.
- 1.45. “Know-How”** means any invention, technology, discovery, development, data, results, information, process, method, techniques, protocols, trade secrets, practices, specifications, formulations, formulae, materials, compositions of matter, non-clinical reports, clinical reports, regulatory submission documents and summaries, or other know-how, whether or not patentable.

- 1.46. “Knowledge”** means the actual knowledge of the individuals listed on Schedule 1.46 but is not meant to require or imply that any particular inquiry or investigation has been undertaken, including, without limitation, obtaining any type of search (independent of that performed by the actual Governmental Authority during the normal course of patent prosecution, as applicable, in a jurisdiction) or opinion of counsel.
- 1.47. “Licensed Know-How”** means all Know-How Controlled by Pfizer as of the Effective Date and listed on Schedule 1.47 specific to the Compounds and Products. Licensed Know-How excludes [***] Know-How Controlled by Pfizer that is not specific to the Compounds or Products as they exist as of the Effective Date.
- 1.48. “Licensed Patent Rights”** means all Patent Rights listed on Schedule 1.48.
- 1.49. “Licensed Technology”** means, collectively, the Licensed Patent Rights and Licensed Know-How.
- 1.50. “Major Market Country”** means any of France, Germany, Italy, Japan, Spain, the United Kingdom or the United States.
- 1.51. “Manufacture” or “Manufacturing”** means to make, produce, manufacture, process, fill, finish, package, label, perform quality assurance testing, release, ship or store a compound or product or any component thereof. When used as a noun, “Manufacture” or “Manufacturing” means any and all activities involved in Manufacturing a compound or product or any component thereof.

1.52. “**Milestone Payments**” means, collectively, the [***] Milestone Payments and Sales Milestone Payments.

1.53. “**NDA**” means, with respect to a pharmaceutical product, a New Drug Application submitted to the FDA in accordance with the FD&C Act, and the rules and regulations promulgated thereunder, or any analogous application or submission with any Regulatory Authority outside of the United States.

1.54. “**Net Sales**” means, with respect to all Products distributed or sold in the Territory to Third Parties by Licensee, its Affiliates and sublicensees, the gross receipts from sales of such Products in the Territory, less in each case: (a) sales returns and allowances actually paid, granted or accrued, including trade, quantity and cash discounts and other adjustments, including those granted on account of price adjustments, returns, rebates, chargebacks or similar payments granted or given to wholesalers or other institutions, (b) adjustments arising from consumer discount programs or other similar programs, (c) customs or excise duties, value-added taxes, sales taxes, consumption taxes or other taxes (except income taxes) or duties relating to sales, or any payment in respect of sales provided such duties or taxes are recorded in gross sales, or (d) any payment in respect of sales to the United States government, any state government or any foreign government, or to any other Governmental Authority, or with respect to any government-subsidized program or managed care organization. Net Sales shall be determined from the Licensee’s books and records maintained in accordance with GAAP consistently applied.

Resales or sales of a Product made in good faith between or among Licensee, any of its Affiliates or any of its sublicensees shall not be included in the calculation of Net Sales, but the first sale thereafter to a Third Party (other than a sublicensee) shall be included in the calculation of Net Sales.

Notwithstanding the foregoing, in the event a Product is sold in a country in the Territory as a Combination Product, Net Sales of the Combination Product will be calculated as follows:

- i. If the Compound contained in a Combination Product is sold separately as a Product (a “**Compound Product**”) in such country and the other therapeutically active ingredients contained in the Combination Product (“**Other Active Ingredient(s)**”) are also sold separately in such country, Net Sales will be calculated by multiplying the total Net Sales (as described above) of the Combination Product by the fraction $A/(A+B)$, where A is the average gross selling price in such country of the Compound Product sold separately in the same formulation and dosage, and B is the average gross selling price in such country of such Other Active Ingredient(s) during the applicable Calendar Year.
- ii. If the Compound Product contained in the Combination Product is sold independently of the Other Active Ingredient(s) contained in the Combination Product in such country, but the average gross selling price of such Other Active Ingredient(s) in such country cannot be determined, Net Sales will be calculated by multiplying the total Net Sales (as described above) of the Combination Product by the fraction A/C where A is the average gross selling price in such country of such Compound Product sold independently and C is the average gross selling price in such country of the entire Combination Product, during the applicable Calendar Year.
- iii. If the Other Active Ingredient(s) contained in the Combination Product are sold independently in such country, but there is no applicable Compound Product in such country (i.e., the Compound contained in the Combination Product is not sold separately as a Product in such country) or the average gross selling price of the applicable Compound Product in such country cannot be determined, Net Sales will be calculated by multiplying the total Net Sales (as described above) of the Combination Product by the fraction $(1-(B/C))$, where B is the average gross selling price in such country of such Other Active Ingredient(s) and C is the average gross selling price in such country of the entire Combination Product, during the applicable Calendar Year.

- iv. If there is no applicable Compound Product contained in the Combination Product and the Other Active Ingredient(s) contained in the Combination Product are not sold separately in such country, or the average gross selling price of neither such Compound Product nor such Other Active Ingredient(s) can be determined in such country, then Net Sales of the Combination Product in such country will be calculated by mutual agreement of the Parties; *provided*, that if the Parties cannot reach mutual agreement prior to the end of an applicable accounting period, such matter shall be resolved in accordance with Section 16.1.
- 1.55. **“Partner”** means any of Licensee’s sublicensees and assignees and its other strategic or commercial partners or transferees (but not distributors) of rights to the Compound, a Product or the Licensed Technology.
- 1.56. **“Party”** and **“Parties”** is defined in the introduction to this Agreement.
- 1.57. **“Patent Rights”** means any and all (a) issued patents, (b) pending, inactive, or abandoned patent applications, including all provisional applications, existing and future divisions, continuations, substitutions, continuations-in-part and renewals, and all patents granted thereon, (c) of the foregoing patents or patent applications, any patents-of-addition, re-examinations, reissues and extensions or restorations by existing or future extension or restoration mechanisms, including patent term adjustments, patent term extensions, revalidations, supplementary protection certificates or the equivalent thereof, (d) inventor’s certificates, (e) other forms of government-issued rights substantially similar to any of the foregoing, and (f) United States and foreign counterparts of any of the foregoing.
- 1.58. **“Person”** means an individual, corporation, partnership, limited liability company, trust, business trust, association, joint stock company, joint venture, pool, syndicate, sole proprietorship, unincorporated organization, Governmental Authority or any other form of entity not specifically listed herein.
- 1.59. **“Pfizer Indemnitees”** is defined in Section 11.1.
- 1.60. **“Phase I Clinical Trial”** means a clinical trial that generally provides for the first introduction into humans of a pharmaceutical product with the primary purpose of determining safety, metabolism and pharmacokinetic properties and clinical pharmacology of such product, in a manner that is generally consistent with 21 CFR § 312.21(a), as amended (or its successor regulation).
- 1.61. **“Phase II Clinical Trial”** means a clinical trial, the principal purpose of which is to make a preliminary determination as to whether a pharmaceutical product is safe for its intended use and to obtain sufficient information about such product’s efficacy, in a manner that is generally consistent with 21 CFR § 312.21(b), as amended (or its successor regulation), to permit the design of further clinical trials.

- 1.62. **“Phase III Clinical Trial”** means a pivotal clinical trial with a defined dose or a set of defined doses of a pharmaceutical product designed to ascertain efficacy and safety of such product, in a manner that is generally consistent with 21 CFR § 312.21(c), as amended (or its successor regulation), for the purpose of enabling the preparation and submission of an NDA.
- 1.63. **“Product”** means any pharmaceutical product in any form or formulation suitable for administration to patients which contains the Compound as an active pharmaceutical ingredient.
- 1.64. **“Receiving Party”** is defined in Section 9.1.
- 1.65. **“Recipients”** is defined in Section 9.2.
- 1.66. **“Regulatory Approval”** means, with respect to a Product in any country or jurisdiction, any approval, registration, license or authorization that is required by the applicable Regulatory Authority to market and sell such Product in such country or jurisdiction. Regulatory Approvals include approvals by Regulatory Authorities of INDs or NDAs.
- 1.67. **“Regulatory Authority”** means any Governmental Authority responsible for granting Regulatory Approvals for a Product in the Territory.

- 1.68. “**Regulatory Filings**” means, with respect to a Product, any submission to a Regulatory Authority of any appropriate regulatory application, including, without limitation, any IND, or NDA,) or any foreign equivalents thereof, any submission to a regulatory advisory board, any marketing authorization application, and any supplement or amendment thereto.
- 1.69. “**Relevant Records**” is defined in Section 6.1.
- 1.70. “**Residuals**” is defined in Section 2.4.
- 1.71. “**Review Period**” is defined in Section 14.3.
- 1.72. “**Royalties**” is defined in Section 5.5.
- 1.73. “**Royalty Term**” means, with respect to each Product in each country in the Territory, the period commencing on the First Commercial Sale of such Product in such country and expiring upon latest to occur of: (a) twelve (12) years following the date of First Commercial Sale of such Product in such country, (b) the expiration of all regulatory or data exclusivity in such country for such Product or (c) the date upon which the manufacture, use, sale, offer for sale or importation of such Product in such country would no longer infringe, but for the license granted herein, a Valid Claim of a Licensed Patent Right.

- 1.74. “**Sales Milestone**” is defined in Section 5.4.
- 1.75. “**Sales Milestone Payment**” is defined in Section 5.4.
- 1.76. “**SEC Filing**” is defined in Section 9.3.2.
- 1.77. “**Shares**” is defined in Section 5.1.
- 1.78. “**Sublicensing Income**” means any and all consideration in any form paid to Licensee by a Partner who is a sublicensee for the grant of a Sublicense under the Licensed Technology, including but not limited to upfront fees, success fees, license issue fees, license maintenance fees, fees for transfer of intellectual property, royalties on sales of Product (solely in excess of the Royalties set forth in 5.5) *provided that* Sublicensing Income shall expressly not include (a) royalties that are equal to or less than those set forth in Section 5.5; (b) payments received by Licensee (as properly documented by Licensee and subject to audit) in connection with research, development or supply activities under joint ventures, partnerships or collaboration agreements where Licensee or an Affiliate is obligated to perform research, development or supply activities for any Product; (c) other payments made by a Partner as consideration for Licensee’s or an Affiliate’s performance of services (e.g., to a CRO or CMO) or provision of goods; (d) reimbursement of actual patent prosecution, maintenance, enforcement or defense expenses; (e) loans to Licensee unless and until such loaned amount becomes forgiven; (f) payments based on a profit share interest paid in consideration for Licensee’s or its Affiliate’s payment of development or commercialization expenses; and (g) amounts paid for purchase of securities of Licensee to the extent that such payment does not exceed the fair market value of such securities.
- 1.79. “**Tax Action**” is defined in Section 5.12.1.
- 1.80. “**Term**” is defined in Section 13.1.
- 1.81. “**Territory**” means worldwide.
- 1.82. “**Third Party**” means any Person other than a Party or an Affiliate of a Party.
- 1.83. “**Third Party Infringement**” is defined in Section 8.1.
- 1.84. “**Third Party License**” is defined in Section 5.7.1

1.85. “United States”, “US” or “U.S.” means the United States of America, including its districts, territories and possessions.

1.86. “Upfront Payment” is defined in Section 5.1.

1.87. “Valid Claim” means with respect to a particular country, a claim of a Patent Right within the Licensed Patent Rights that: (a) with respect to an issued and unexpired patent, (i) has not been held permanently revoked, unenforceable or invalid by a decision of a court or other Governmental Authority of competent jurisdiction, which decision is unappealable or has not been appealed within the time allowed for appeal and (ii) has not expired or been cancelled, withdrawn, abandoned, disclaimed or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise and (iii) has not lapsed; and (b) with respect to a pending patent application, (i) has not been abandoned or finally disallowed without the possibility of appeal or refiling of such application and (ii) with respect to any patent application for which Licensee has provided Pfizer an Election Notice pursuant to Section 7.2.4 and which Pfizer has elected to continue prosecuting, is not pending more than [***] after receipt by Pfizer of such Election Notice.

1.88. “VAT” is defined in Section 5.12.1.

1.89. **Interpretation.** Except where the context expressly requires otherwise, (a) the use of any gender herein shall be deemed to encompass references to any gender, and the use of the singular shall be deemed to include the plural (and vice versa), (b) the words “include”, “includes”, “including”, and “e.g.” shall be deemed to be followed by the phrase “without limitation”, (c) the word “will” shall be construed to have the same meaning and effect as the word “shall”, (d) 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), (e) any reference herein to any Person shall be construed to include the Person’s successors and assigns, (f) the words “herein”, “hereof” and “hereunder”, and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (g) all references herein to Sections, Exhibits or Schedules shall be construed to refer to Sections, Exhibits or Schedules of this Agreement, and references to this Agreement include all Exhibits and Schedules hereto, (h) the word “notice” means notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement, (i) provisions that require that a Party, the Parties or any committee hereunder “agree,” “consent” or “approve” or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (but excluding e-mail and instant messaging), (j) references to any specific law, rule or regulation, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof, and (k) the term “or” shall be interpreted in the inclusive sense commonly associated with the term “and/or.”

2. LICENSE GRANT.

2.1. License Grant.

2.1.1. Licensed Patent Rights. Subject to the terms and conditions of this Agreement, Pfizer on behalf of itself and its Affiliates hereby:

- (a) Grants to Licensee an exclusive (even as to Pfizer and its Affiliates), sublicensable (subject to Section 2.2), royalty-bearing right and license under the Licensed Patent Rights to use, have used, Develop, have Developed, Manufacture, have Manufactured, Commercialize, have Commercialized and otherwise exploit the Compound and Products in the Field within the Territory. For the avoidance of doubt, the license grant

set forth in this Section 2.1.1(a) does not include a license under Patent Rights that [***] are not set forth on Schedule 1.19.

- (b) Grants to Licensee a [***] license to the targeted [***] Patent Rights and Know-How jointly Controlled by Pfizer and [***] solely to use, have used, Develop, have Developed, Manufacture, have Manufactured, Commercialize, have Commercialized and otherwise exploit the Compound and Products in the Field within the Territory, such license is exercisable as of the date [***] and Licensee enter into an agreement whereby [***] grants to Licensee a license under [***] to use, have used, Develop, have Developed, Manufacture, have Manufactured, Commercialize, have Commercialized and otherwise exploit the Compound and Products in the Field within the Territory [***]. For the avoidance of doubt, the license from Pfizer under the [***].

2.1.2. Licensed Know How. Subject to the terms and conditions of this Agreement, Pfizer on behalf of itself and its Affiliates hereby grants to Licensee a non-exclusive sublicensable (subject to Section 2.2), royalty-bearing right and license to use the Licensed Know-How for the sole purpose of (a) the use, Development, Commercialization, Manufacture or exploitation of Compounds or Products by or on behalf of Licensee in the Field within the Territory and (b) to prosecute and maintain Patent Rights that claim or cover any of the Compounds, Products or Licensed Know-How. For the avoidance of doubt, the license grant set forth in this Section 2.1.2 does not include a license under Licensed Know How for [***] the Compounds that are not set forth on Schedule 1.19.

2.1.3. Affiliates. To the extent any of the Licensed Technology is Controlled by an Affiliate of Pfizer, then promptly following the Effective Date, Pfizer shall cause such Affiliate to take all necessary actions to give effect to the licenses granted under this Section 2.1.

2.2. Sublicense Rights.

2.2.1. Licensee may sublicense (directly through multiple tiers or to authorize sublicenses through multiple tiers) or divest the rights granted to it by Pfizer under this Agreement to any of its Affiliates without Pfizer's approval or to any Third Party upon Pfizer's prior written approval, such approval shall not be unreasonably withheld, conditioned, or delayed. Any and all sublicenses shall be subject to the following requirements:

2.2.2. All sublicenses shall be subject to and consistent with the terms and conditions of this Agreement and shall: (a) preclude the assignment of such sublicense without the prior written approval of Pfizer such approval shall not be unreasonably withheld, conditioned, or delayed, (b) include Pfizer as a third party beneficiary under the sublicense with the right to enforce the terms of such sublicense, and (c) preclude the granting of further sublicenses in contravention with the terms and conditions of this Agreement. In no event shall any sublicense relieve Licensee of any of its obligations under this Agreement.

2.2.3. Licensee shall furnish to Pfizer a true and complete copy of each sublicense agreement with a non-Affiliate sublicensee and each amendment thereto, within [***] after the sublicense or amendment has been executed.

2.3. Retained Rights. Licensee acknowledges and agrees that (a) Pfizer retains the right to make, have made, use and import the Compound and Product solely for all internal research purposes, [***].

2.4. Residuals. Pfizer may use for any purpose the Residuals resulting from access to or work with the Compound or Products and Licensed Know-How. As used herein, "**Residuals**" means information in non-tangible form which may be retained in the unaided memories of the relevant Party's employees or consultants who have had access to a Product and Licensed Know-How for reasons other than memorizing the same, including such information in the form of ideas, concepts, know-how or techniques.

2.5. No Additional Rights. Nothing in this Agreement shall be construed to confer any rights upon Licensee by implication, estoppel, or otherwise as to any technology or Intellectual Property Rights of Pfizer or its Affiliates other than the rights in Licensed Technology expressly granted herein, regardless of whether such technology or Intellectual Property Rights shall be dominant or subordinate to any Licensed Technology.

3. **TRANSFER ACTIVITIES.** Schedule 3 sets forth the documentation and materials that Pfizer will transfer to Licensee as well as the related activities to be performed by the Parties.

4. **DEVELOPMENT; COMMERCIALIZATION; MANUFACTURING.**

4.1. **General.** Licensee shall have sole responsibility for the cost and expense of, and the sole authority over and control of, the Development, Manufacture, Regulatory Approval and Commercialization of Compounds and Products in the Field.

4.2. **Diligence.**

4.2.1. **Development.** Licensee shall itself, or through its Affiliates or sublicensees, use Commercially Reasonable Efforts to Develop and seek Regulatory Approval for a Product in the United States [***].

4.2.2. **Commercialization.** Licensee shall itself, or through its Affiliates or sublicensees, use Commercially Reasonable Efforts to Commercialize one Product in each Major Market Country in the Territory where Licensee or its designated Affiliates or sublicensees receive Regulatory Approval for such Product.

4.3. **Regulatory Filings.** In connection with its efforts to Develop a Product, Licensee shall bear all responsibility and expense and have sole authority and control over, submitting Regulatory Filings and obtaining Regulatory Approval for such Product. Licensee will undertake such activities at its sole expense. Upon the effective date of transfer of the Regulatory Filings pursuant to Section 3, Licensee shall be responsible, at its sole discretion, for maintaining at its sole expense such Regulatory Filings transferred to Licensee pursuant to Schedule 3. As between the Parties, Licensee will own any and all applications for Regulatory Approvals and other Regulatory Filings related to any Compound or Product which are filed by or on behalf of Licensee. Licensee will have the sole right to conduct all communications with Regulatory Authorities, including all meetings, conferences and discussions, with regard to the Compound and Products in the Territory.

4.4. **[***] Reporting.** At least [***]. Licensee's obligations to provide [***] reports under this Section 4.4 shall automatically expire on the date of the First Commercial Sale of a Product.

4.5. **U.S. Manufacturing.** Licensee agrees that, to the extent required, it shall comply with the applicable requirements of 35 U.S.C. § 204 in connection with Manufacturing a Product.

4.6. **CROs and CMOs.** Licensee may contract Third Party CROs or CMOs to handle certain clinical Development or Manufacture activities, in Licensee's reasonable discretion, consistent with the then-current Development Plan. As between the Parties, all costs of CROs or CMOs will be borne solely by Licensee. For clarity, Licensee shall not be required to obtain Pfizer's consent of a sublicense to a CRO or CMO if with respect to the use of the Licensed Technology the applicable contract is (a) in the case of a CRO, limited to a license for such CRO to perform research with regard to a Product on behalf of Licensee or (b) in the case of a CMO, limited to a license for such CMO to Manufacture Product on behalf of Licensee.

4.7. **Development Plan.** All Development and Commercialization activities to be conducted in connection with any Compound or Product will be performed by Licensee consistent with the terms and conditions set forth in this Section 4.7 and the development plan as set forth in Schedule 4.7, as amended by Licensee pursuant to this Section 4.7 (the "Development Plan"). Each updated Development Plan shall include [***]. The foregoing obligations shall expire upon the date of the First Commercial Sale of a Product in each of the U.S. and one other country in the Major Market Countries.

4.8. ~~***~~.

4.9. **Supply to Research Institutions.** Licensee agrees to supply ~~***~~ Compounds or Products requested by the Third Parties who are a party to the agreements set forth on Schedule 4.9 in accordance with the terms of those agreements. Licensee will be liable for any and all obligations and liabilities, and will indemnify, hold harmless and defend the Pfizer Indemnitees in accordance with Section 11.1, related to the supply of Compounds and Products to any Third Party in accordance with this Section 4.9.

5. **PAYMENT TERMS.**

5.1. **Equity.** In consideration of the licenses and rights granted to Licensee hereunder, Licensee will issue and grant to Pfizer such number of shares of the Licensee’s common stock equivalent in monetary value on an aggregate basis to five million U.S. dollars (\$5,000,000), where the number of shares of Licensee’s common stock issued to Pfizer shall be calculated by dividing five million U.S. dollars (\$5,000,000) by the closing price of a share of Licensee’s common stock on the NASDAQ Capital Market on the Effective Date, rounded to the nearest whole share.

5.2. **Upfront Payment.** In consideration of the licenses and rights granted to Licensee hereunder, Licensee shall pay to Pfizer a one-time, upfront, non-refundable and non-creditable payment of five million U.S. dollars (\$5,000,000.00) within ~~***~~ following the Effective Date (“**Upfront Payment**”).

5.3. ~~***~~ **Milestone Payments.** In consideration of the licenses and rights granted to Licensee hereunder, Licensee shall pay to Pfizer the amounts set forth below within ~~***~~ following the first achievement of each event described below for the applicable Product (each event, a “~~***~~ **Milestone**” and each payment, a “~~***~~ **Milestone Payment**”).

*** MILESTONE	*** MILESTONE PAYMENT
(1) ***	***
(2) ***	***
(3) ***	***
(4) ***	***
(5) ***	***
(6) ***	***
(7) ***	***
(8) ***	***

The total amount of Development Milestone Payments shall not exceed ~~***~~. For the avoidance of doubt ~~***~~:

If a ~~***~~ Milestone is achieved without achieving a ~~***~~ Milestone that would otherwise have occurred prior to the ~~***~~ Milestone that was achieved, then all prior ~~***~~ Milestones shall be deemed to have been achieved, and if not previously paid, the corresponding ~~***~~ Milestone Payments shall become payable.

5.4. **Sales Milestone Payments.** In consideration of the licenses and rights granted to Licensee hereunder, Licensee shall pay to Pfizer the following one-time payments when aggregate Net Sales of Products in the Territory during a Calendar Year first reach the respective thresholds indicated in the table below (each event, a “**Sales Milestone**” and each payment, a “**Sales Milestone Payment**”).

SALES MILESTONE	SALES MILESTONE PAYMENT
Aggregate Net Sales during a Calendar Year of all Products first exceed ***	***
Aggregate Net Sales during a Calendar Year of all Products first exceed ***	***
Aggregate Net Sales during a Calendar Year of all Products first exceed ***	***

Aggregate Net Sales during a Calendar Year first exceed [***]	[***]
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The total amount of Sales Milestone Payments shall not [***]. Each of the above Sales Milestone Payments shall be paid only once upon the first achievement of the applicable Sales Milestone, regardless of the number of times such Sales Milestone is achieved. Only Net Sales on which a Royalty is due shall be considered for purposes of determining whether a Sales Milestone has been achieved. Licensee shall make any Sales Milestone Payment payable within [***] after the end of the applicable Calendar Quarter in which Net Sales reach the applicable threshold, and such payment shall be accompanied by a report identifying the amount payable to Pfizer under this Section 5.4.

5.5. Royalty Payments. In consideration of the licenses and rights granted to Licensee hereunder, Licensee shall pay to Pfizer royalties in the amount of the Marginal Royalty Rates (set forth in the table below) on the aggregate Net Sales resulting from the sale of Products, on a Product-by-Product basis, in the Territory during each Calendar Year (collectively, “Royalties”).

NET SALES	MARGINAL ROYALTY RATE
Net Sales up to and including [***] per Calendar Year	[***]
Net Sales above [***] up to and including [***] per Calendar Year	[***]
Net Sales above [***] per Calendar Year	[***]

Each Marginal Royalty Rate set forth in the table above shall apply only to that portion of the Net Sales of each Product in the Territory during a given Calendar Year that falls within the indicated range. Only Net Sales on which a Royalty is due shall be considered for purposes of determining the relevant Marginal Royalty Rate. Licensee shall pay to Pfizer the applicable Royalties within [***] following the expiration of each Calendar Quarter after the date of the First Commercial Sale. Royalties will be payable on a Product-by-Product and country-by-country basis during the Royalty Term for such Product in each country until the expiration of the Royalty Term for such Product in each country. All Royalty payments shall be accompanied by a report that includes reasonably detailed information regarding a total monthly sales calculation of Net Sales of Product (including all deductions) and all Royalties payable to Pfizer for the applicable Calendar Quarter (including any foreign exchange rates employed).

5.6. Sublicensing Income. In consideration of the licenses and rights granted to Licensee hereunder, Licensee shall pay to Pfizer the percentages set forth below of all Sublicensing Income received from any Partner.

TIME PERIOD OF PARTNERING TRANSACTION	SUBLICENSING INCOME PAYMENT RATE
(1) From the Effective Date until [***]	[***]
(2) From [***]	[***]
(3) Following [***]	[***]

Licensee shall make Sublicensing Income payments based on Sublicensing Income received during each Calendar Quarter within [***] following the expiration of each such Calendar Quarter. All payments shall be accompanied by a report that includes a calculation of all Sublicensing Income payments payable to Pfizer for the applicable Calendar Quarter.

5.7. Royalty Deductions.

5.7.1.Expiration of Valid Claims. If, on a country-by-country and Product-by-Product basis, the manufacture, use, sale, offer for sale or importation of such Product in such country would no longer infringe a Valid Claim of a

Licensed Patent Right, and Applicable Law requires a step-down in the Marginal Royalty Rate to avoid a claim of patent misuse and such requirement is not satisfied by Section 5.7.3, then the Marginal Royalty Rate with respect to such Product in such country shall be reduced by [***].

5.7.2. Third Party Licenses. Licensee, its Affiliate or sublicensees shall have the right to obtain a license under any Third Party Patent Rights or Know-How that Licensee, or any of its Affiliates or sublicensees, deems reasonably necessary or useful in order to use, Develop, Manufacture, Commercialize or exploit any Compound or Product in the Territory (each such license, a “**Third Party License**”). Licensee, or its applicable Affiliate or sublicensee, shall pay all amounts due under Third Party Licenses; *provided*, that Licensee shall be entitled to reduce the Royalties due to Pfizer upon Net Sales of Products by up to [***] of the royalties paid by Licensee, or any of its Affiliates or sublicensees to a Third Party with respect to such Product under any Third Party License.

5.7.3. Generic Competition. If at any time during the Royalty Term Generic Competition exists in a given country with respect to a Product, then the Marginal Royalty Rates used to calculate Royalties for such Product in such country shall be reduced by [***] for so long as such Generic Competition exists.

5.7.4. Maximum Deductions. Notwithstanding Sections 5.7.1, 5.7.2 and 5.7.3 to the contrary, under no circumstances shall the reductions set forth in Section 5.7 cause the total Royalties payable to Pfizer in any Calendar Quarter to be reduced by more than [***] of the amount that would otherwise be due without giving effect to this Section 5.7. Licensee may carry forward to subsequent Calendar Quarters any deductions under this Section 5.7 that were not previously deducted by Licensee.

5.8. Other Payments. Licensee shall pay to Pfizer any other amounts due under this Agreement within [***] following receipt of an invoice.

5.9. Late Payments. Any amount required to be paid by a Party hereunder which is not paid on the date due shall bear interest, to the extent permitted by law, [***] effective for the date such payment was due, or the Secured Overnight Financing Rate once the [***] has been phased out, in each case of each rate, as reported in the Wall Street Journal. Such interest shall be computed on the basis of a year of three hundred sixty (360) days for the actual number of days payment is delinquent.

5.10. Currency. Any payments under this Section 5 that are recorded in currencies other than the U.S. Dollar shall be converted into U.S. Dollars at the average of the daily foreign exchange rates published in the Wall Street Journal (or any other qualified source that is acceptable to both Parties) for the Calendar Quarter in which such payments or expenses occurred, or for periods less than a Calendar Quarter, the average of the daily rates published in the Wall Street Journal for such period.

5.11. Method of Payment. All payments from Licensee to Pfizer shall be made by wire transfer via immediately available funds in U.S. dollars to credit the bank account set forth below or such other bank account as designated by Pfizer in writing to Licensee at least [***] before payment is due. Any payment which falls due on a date which is not a Business Day may be made on the next succeeding Business Day.

[Account Information Omitted]

5.12. Taxes.

5.12.1. General. It is understood and agreed between the Parties that any payments made under this Agreement are exclusive of any value added or similar tax (“VAT”), which shall be added thereon as applicable. In the event any payments made by Licensee to Pfizer pursuant to this Agreement become subject to withholding taxes under the laws or regulation of any jurisdiction, Licensee shall deduct and withhold the amount of such taxes for the account of Pfizer to the extent required by Applicable Law and such amounts payable to Pfizer shall be reduced by the amount of taxes deducted and withheld, which shall be treated as paid to Pfizer in accordance with this Agreement. To the extent that Licensee is required to deduct and withhold taxes on any payments under this Agreement, Licensee shall pay the amounts of such taxes to the proper Governmental Authority in a timely

manner and promptly transmit to the payee an official tax certificate or other evidence of such withholding sufficient to enable Pfizer to claim such payments of taxes. Pfizer shall provide any tax forms to Licensee that may be reasonably necessary in order for Licensee not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. Each Party shall provide the other with reasonable assistance to enable the recovery, as permitted by Applicable Law, of withholding taxes, VAT, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax or VAT.

5.12.2. Tax Actions. Notwithstanding anything in this Agreement to the contrary, if (a) an action, including but not limited to any assignment or sublicense of its rights or obligations under this Agreement, or, or (b) any failure to comply with Applicable Laws or filing or record retention requirements (either (a) or (b), a “**Tax Action**”) by a Party leads to the imposition of withholding tax liability or VAT on the other Party that would not have been imposed in the absence of a Tax Action or in an increase in such liability above the liability that would have been imposed in the absence of such Tax Action, then (i) the sum payable by the Party that caused the Tax Action (in respect of which such deduction or withholding is required to be made) shall be increased to the extent necessary to ensure that the other Party receives a sum equal to the sum which it would have received had no Tax Action occurred and (ii) the sum payable by the Party that caused a Tax Action (in respect of which such deduction or withholding is required to be made) shall be made to the other Party after deduction of the amount required to be so deducted or withheld, which deducted or withheld amount shall be remitted in accordance with Applicable Law. For the avoidance of doubt, a Party shall only be liable for increased payments pursuant to this Section 5.12.2 to the extent such Party engaged in a Tax Action that created or increased a withholding tax or VAT on the other Party.

5.12.3. Cooperation. The Parties agree to cooperate and produce on a timely basis any tax forms or reports, including an IRS Forms W-9 and W-8BEN, reasonably requested by the other Party in connection with any payment made by Licensee to Pfizer under this Agreement.

6. RECORDS; AUDIT RIGHTS.

6.1. Relevant Records. Licensee shall maintain accurate financial books and records pertaining to sale of a Product by Licensee, its Affiliates or sublicensees, as applicable, including any and all calculations of the applicable Fees (collectively, “**Relevant Records**”). The relevant Person shall maintain the Relevant Records for the longer of: (a) the period of time required by Applicable Law, or (b) [***] following the end of the Calendar Year to which they relate.

6.2. Audit Request. Pfizer shall have the right during the term of this Agreement and for [***] thereafter to engage, at its own expense, an independent auditor that is reasonably acceptable to Licensee to examine the Relevant Records from time-to-time, but no more frequently than once [***], as may be necessary to verify compliance with the provisions of Section 5 or any other payments described in this Agreement. Such audit shall be requested in writing at least [***] in advance and shall be conducted during Licensee’s normal business hours, in the location where such Relevant Records are normally kept, and otherwise in a manner that minimizes any interference to Licensee’s business operations. Prior to conducting such audit, the independent auditor shall enter into a reasonable and customary confidentiality agreement with Licensee. The results of such audit shall be made available to Licensee at the same time as such results are made available to Pfizer.

6.3. Audit Fees and Expenses. Pfizer shall bear any and all fees and expenses it may incur in connection with any such audit of the Relevant Records; *provided, however*, in the event an audit reveals an underpayment by Licensee of more than [***] as to the period subject to the audit, Licensee shall reimburse Pfizer for any reasonable and documented out-of-pocket costs and expenses of the audit within [***] after receiving invoices therefor, and notwithstanding the provisions

of Section 6.2, Pfizer shall have the right to examine the Relevant Records of Licensee up to once [***] following the audit revealing such underpayment.

6.4. Payment of Deficiency. If any such audit establishes that Licensee underpaid any amounts due to Pfizer under this Agreement, then Licensee shall pay Pfizer any such deficiency within [***] after receipt of written notice thereof and the relevant audit report. For the avoidance of doubt, such payment will be considered a late payment, subject to Section 5.9.

7. INTELLECTUAL PROPERTY RIGHTS.

7.1. Pre-existing IP. Subject only to the rights expressly granted to the other Party under this Agreement, each Party shall retain all rights, title and interests in and to any Intellectual Property Rights that are owned by, licensed or sublicensed to such Party prior to or independent of this Agreement.

7.2. Patent Prosecution.

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7.2.1. Patent Prosecution and Maintenance of Pfizer Licensed Patent Rights. Subject to Pfizer's rights set forth in Section 7.2.3 below, and immediately upon Pfizer's transfer of the documentation related to the Licensed Patent Rights in accordance with Schedule 3, Licensee will be responsible for filing, prosecuting (including in connection with any reexaminations, oppositions and the like), maintaining, and enforcing the Licensed Patent Rights in the Territory, in Pfizer's name at Licensee's own cost and expense using [***] as lead patent counsel and [***] annuity service provider to prepare, file, prosecute and maintain the Licensed Patent Rights. Licensee will select additional qualified patent counsel and foreign agents as necessary, in each case reasonably acceptable to Pfizer, such acceptance not to be unreasonably withheld, conditioned or delayed. During the Term, Licensee will provide notice of any substitution of such counsel, foreign agents or annuity service within [***] after such substitution. Before each submission with respect to a Pfizer Licensed Patent Right is filed, Licensee will provide Pfizer a reasonable opportunity to review and comment on proposed submissions to any patent office and reasonably consider any comments provided by Pfizer to Licensee. Licensee will keep Pfizer reasonably informed of the status of the Licensed Patent Rights by timely providing Pfizer copies of significant communications relating to such Licensed Patent Rights that are received from any patent office or patent counsel of record or foreign associate. Without limiting the foregoing, Licensee may prepare, file, prosecute and maintain Patent Rights that claim or cover Licensed Know-How and to the extent any such Patent Rights claim or cover joint inventions of the Parties, notwithstanding anything herein to the contrary, (a) Pfizer's interest in the same shall be included in Licensed Patent Rights, (b) each Party shall have an undivided one-half interest in and to such Patent Rights, (c) each Party may exercise its ownership rights in and to such Patent Rights, including the right to license and sublicense or otherwise to exploit, transfer, or encumber its ownership interest, without an accounting or obligation to, or consent required from, the other Party, but subject to the licenses hereunder. At the reasonable written request of a Party, the other Party will in writing grant such consents and confirm that no such accounting is required to effect the foregoing regarding such joint Patent Rights.

7.2.2. Assistance. As reasonably requested by Licensee in writing, Pfizer shall cooperate, at Licensee's expense, in obtaining patent term adjustment, patent term restoration (whether or not under the Drug Price Competition and Patent Term Restoration Act), supplementary protection certificates and patent term extensions, or any equivalents to the foregoing, with respect to the Licensed Patent Rights. For clarity, Licensee shall have the exclusive right, but not the obligation, to seek, in Pfizer's name if so required, or require Pfizer to seek at Licensee's expense, any patent term adjustments, patent term restorations, patent term extensions, supplemental protection certificates and the like in any country in the Territory in relation to the Licensed Patent Rights and Pfizer shall reasonably cooperate in connection with all such activities at Licensee's expense.

7.2.3. Failure to Prosecute or Maintain. In the event Licensee elects to forgo filing, prosecution or maintenance of the Licensed Patent Rights, Licensee shall notify Pfizer of such election at least [***] prior to any filing or payment due date, or any other due date that requires action ("**Election Notice**"). Upon receipt of an Election Notice, Pfizer shall be entitled, upon written notice to Licensee, at its sole discretion and expense, to file or to continue the prosecution or maintenance of such Patent Right in such country or region in Pfizer's name using counsel of its

own choice and at its own expense, in which case, as of the date Licensee provides Pfizer such Election Notice, the license granted in Section 2.1.1 with respect to such Licensed Patent Rights shall continue under a non-exclusive and non-sublicensable (to the extent Licensee has not sublicensed such Patent Right prior to providing such Election Notice), and Licensee will have no further rights in respect of the maintenance or enforcement of such Patent Right.

8. INFRINGEMENT; MISAPPROPRIATION.

8.1. Notification. Each Party will promptly notify the other Party in writing of (a) any actual or threatened infringement, misappropriation or other violation by a Third Party of any Licensed Technology in the Field and in the Territory of which it becomes aware, including the filing of an Abbreviated New Drug Application under Section 505(j) of the FD&C Act, as amended or supplemented, or an application under Section 505(b)(2) of the FD&C Act, as amended or supplemented, naming a Product as a reference listed drug and including a certification under Section 505(j)(2)(A)(vii)(IV) or 505(b)(2)(A)(IV), respectively, or (b) declaratory judgment action against any Licensed Patent Right in the Territory in connection with any infringement described in clause (a) (any of (a) or (b) constituting a “Third Party Infringement”).

8.2. Infringement Action.

8.2.1. Right of First Enforcement.

(a) Licensee, itself or through any of its Affiliates or sublicensees, shall have the first right (but not the obligation), at its own expense, to control enforcement of the Licensed Technology against any Third Party Infringement within the scope of its exclusive license and may name Pfizer as a party for standing purposes. Prior to commencing any such action, Licensee shall consult with Pfizer and shall give due consideration to Pfizer’s recommendations regarding the proposed action. Licensee shall give Pfizer timely notice of any proposed settlement of any such action instituted by Licensee and shall not, without the prior written consent of Pfizer, enter into any settlement that would: (i) adversely affect the validity, enforceability or scope of any of the Licensed Patent Rights, (ii) give rise to liability of Pfizer or its Affiliates, (iii) admit non-infringement of any Licensed Patent Rights, or (iv) otherwise impair Pfizer’s rights in any Licensed Technology or this Agreement.

(b) If Licensee does not, with respect to its first right of enforcement under Section 8.2.1(a), obtain agreement from the alleged infringer to desist or fails or refuses to initiate an infringement action by the earlier of (i) [***] following Licensee’s receipt of notice of the alleged infringement, or (ii) [***] before the expiration date for filing such actions, then Pfizer shall have the right, at its sole discretion, to control such enforcement of the Licensed Technology at its sole expense.

8.2.2. Recoveries. Any recoveries resulting from an action relating to a claim of Third Party Infringement shall first be applied to reimburse each Party’s (and Licensee’s Affiliates’ and sublicensees’, as applicable) costs and expenses incurred in connection therewith. Any remaining recoveries shall be retained by (or if received by Pfizer, paid to) Licensee; *provided, however*, Pfizer shall be entitled to a royalty on such remaining recoveries of [***]. If Licensee fails to institute an action or proceeding and Pfizer exercises its right to prosecute such infringement pursuant to Section 8.2.1(b), any remaining recoveries shall be retained by Pfizer.

9. CONFIDENTIALITY.

9.1. Definition. “Confidential Information” of a Party means the existence and provisions of this Agreement and all other proprietary information and data of a financial, commercial or technical nature that the Disclosing Party or any of its

Affiliates has supplied or otherwise made available to the Receiving Party or its Affiliates, which are disclosed in writing or, if disclosed orally or visually, summarized in writing and provided to the Receiving Party after disclosure. “**Disclosing Party**” means the Party who, or the Party whose Affiliate, discloses Confidential Information to the other Party in connection with this Agreement. “**Receiving Party**” means the Party to whom Confidential Information is disclosed in connection with this Agreement. All reports provided by Licensee are Licensee’s Confidential Information. The terms of this Agreement are the Confidential Information of each Party with each Party treated as the Receiving Party with respect thereto. All Licensed Know-How shall be considered Pfizer’s Confidential Information. Confidential Information shall not include information that: (a) is, at the time of disclosure or becomes, after the time of disclosure, known to the public or part of the public domain through no breach of this Agreement by the Receiving Party or any Recipients to whom it disclosed such information; (b) was known to, or was otherwise in the possession of, the Receiving Party prior to the time of disclosure by the Disclosing Party, without an obligation to treat it as confidential; (c) is disclosed to the Receiving Party on a non-confidential basis by a Third Party who is entitled to disclose it without breaching any confidentiality obligation to the Disclosing Party; or (d) is independently developed by or on behalf of the Receiving Party or any of its Affiliates, as evidenced by its written records, without use or access to the Confidential Information.

9.2. Obligations. The Receiving Party will protect all Confidential Information against unauthorized disclosure to Third Parties with the same degree of care as the Receiving Party uses for its own similar information, but in no event less than a reasonable degree of care. The Receiving Party will use Confidential Information of the Disclosing Party solely to exercise rights or satisfy obligations under this Agreement. The Receiving Party may disclose the Confidential Information to its Partners, Affiliates, and their respective directors, officers, employees, subcontractors, current and prospective sublicensees, consultants, attorneys, accountants, advisors and agents (collectively, “**Recipients**”) who have a need to know such information in connection with the exercise of rights or satisfaction of obligations under this Agreement, *provided* that each such Recipient is bound by written or professional obligations of confidentiality and non-use of Confidential Information that are at least as restrictive as those set forth in this Agreement (but of shorter duration if customary under the circumstances). All obligations of confidentiality and non-use under this Agreement shall survive expiration or termination of this Agreement for [***].

9.3. Exceptions.

9.3.1. Disclosure Required by Law. The restrictions set forth in this Section 9 shall not apply to any Confidential Information that the Receiving Party is required to disclose under Applicable Laws or a court order or other order of a Governmental Authority, *provided* that the Receiving Party: (a) provides the Disclosing Party with prompt notice of such disclosure requirement if legally permitted, (b) affords the Disclosing Party an opportunity to oppose, limit or secure confidential treatment for such required disclosure and (c) if the Disclosing Party is unsuccessful in its efforts pursuant to subsection (b), discloses only that portion of the Confidential Information that the Receiving Party is legally required to disclose as advised by the Receiving Party’s legal counsel; provided that such information will remain subject to this Section 9 if such information is secured confidential treatment in connection with such disclosure.

9.3.2. SEC Filings. In the event either Party is required to publicly disclose or file this Agreement in accordance with Law or applicable stock exchange regulations (“**SEC Filing**”), this Agreement shall be redacted by the filing Party to the extent permissible upon the advice of legal counsel, and the filing Party shall provide the other Party a copy of such redacted Agreement in advance of such SEC Filing to enable the other Party to review and comment on the scope of such redaction; provided that the filing Party shall consider in good faith any comments provided by such other Party.

9.3.3. Disclosure to Assignee of Payments. In the event that Pfizer wishes to assign, pledge or otherwise transfer its rights to receive some or all of the Milestone Payments or Royalties, Pfizer may disclose to a Third Party

Confidential Information of Licensee in connection with any such proposed assignment, provided that Pfizer shall hold such Third Parties to written obligations of confidentiality and non-use with terms and conditions at least as restrictive as those set forth in this Agreement.

- 9.4. Additional Exceptions.** A Receiving Party may disclose Confidential Information of the Disclosing Party, to the extent reasonably necessary, in connection with (a) prosecuting, maintaining or enforcing any of the Licensed Patent Rights, (b) communicating with Governmental Authorities or submitting Regulatory Filings, including seeking Regulatory Approval of a Product, or (c) in connection with litigation, provided that in each case ((a) through (c)) the Receiving Party gives the Disclosing Party a reasonable opportunity to review the proposed disclosure and the Receiving Party considers in good faith any timely comments provided by the Disclosing Party. Further, a Receiving Party may disclose Confidential Information to actual or prospective acquirers, underwriters, investors, lenders, or other financing sources and any bona fide actual or prospective collaborators, licensors, sublicensees, licensees, CROs, CMOs or strategic partners and to directors, officers, employees, agents, consultants, and advisors of any such Third Party, in each case, who are under obligations of confidentiality and non-use with respect to such information that is no less stringent than the terms of this Section 9 (but of duration customary in such circumstances). In addition, Pfizer shall not have a review or approval right with respect to any publication or public presentation by or on behalf of Licensee of any pre-clinical or clinical data contained in the Licensed Know-How.
- 9.5. Right to Injunctive Relief.** Each Party agrees that a breach of this Section 9 may cause irreparable harm to the Disclosing Party and shall entitle the Disclosing Party and the Disclosing Party may, in addition to any other remedies available to it (subject to the terms of this Agreement), seek injunctive relief enjoining such action.
- 9.6. Ongoing Obligation for Confidentiality.** Upon expiration or termination of this Agreement, the Receiving Party shall, and shall cause its Recipients to, destroy or return (as requested by the Disclosing Party) any Confidential Information of the Disclosing Party, except that the Receiving Party (a) may retain a single copy of Disclosing Party's Confidential Information for the sole purpose of (i) ascertaining its rights and responsibilities in respect of such information and (ii) exercising its rights that expressly survive the expiration or termination of this Agreement, and (b) shall not be required to destroy any computer files stored securely by the Receiving Party that are created by automatic system back up.

10. REPRESENTATIONS, WARRANTIES AND COVENANTS.

- 10.1. Representations and Warranties by Each Party.** Each Party represents and warrants to the other Party as of the Effective Date that:
- 10.1.1.** it is a corporation duly organized, validly existing, and in good standing under the laws of its jurisdiction of formation;
- 10.1.2.** it has full corporate power and authority to execute, deliver, and perform under this Agreement, and has taken all corporate action required by Applicable Law and its organizational documents to authorize the execution and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement;
- 10.1.3.** this Agreement constitutes a valid and binding agreement enforceable against it in accordance with its terms;
- 10.1.4.** all consents, approvals and authorizations from all Governmental Authorities or other Third Parties required to be obtained by such Party in connection with this Agreement have been obtained; and
- 10.1.5.** the execution and delivery of this Agreement and all other instruments and documents required to be executed pursuant to this Agreement, and the consummation of the transactions contemplated hereby do not and shall not: (i) conflict with or result in a breach of any provision of its organizational documents, (ii) result in a breach of any agreement to which it is a party that would impair the performance of its obligations hereunder; or (iii) violate any Applicable Law.

- 10.2. Representations and Warranties by Pfizer.** With the exception of the claims described in Schedule 10.2, Pfizer represents and warrants to Licensee as of the Effective Date that:

10.2.1. to its Knowledge, Pfizer has the right to grant the licenses and other rights granted to Licensee under this Agreement;

10.2.2. to Pfizer's Knowledge, there is no ongoing or threatened litigation involving the Licensed Patent Rights.

10.3. Covenants by Licensee.

10.3.1. Licensee covenants to Pfizer that it will use commercially reasonable efforts to obtain the financial and commercial capabilities to Develop and Commercialize the Product and to perform its other obligations in accordance with this Agreement.

10.3.2. Licensee covenants to Pfizer that it shall comply with all Applicable Law with respect to the performance of its obligations hereunder.

10.4. Representations, Warranties and Covenants related to Compliance Laws. Without limiting the generality of Section 10.3.2, Licensee shall comply with the U.S. Foreign Corrupt Practices Act and any other applicable anti-bribery or anti-corruption laws (“**Compliance Laws**”). Licensee represents and warrants that neither Licensee, nor its Affiliates, nor any director, officer, employee, consultant, agent or representative or other person acting on its behalf has taken and covenants that they will not take any action, directly or indirectly, to pay, offer, promise or authorize the payment, or giving of anything of value to any Government Official, or to any person, and has not accepted and covenants that they will not accept a payment for any item of value: (a) for the purpose of (i) influencing any act or decision of such Government Official(s) in their official capacity, including the failure to perform an official function, in order to assist Licensee or its Affiliates or any beneficiary of Licensee in obtaining or retaining business, or directing business to any third party, (ii) securing an improper advantage, (iii) inducing such Government Official(s) to use their influence to affect or influence any act or decision of a government entity in order to assist Licensee, its Affiliates or any beneficiary of Licensee in obtaining or retaining business, or directing business to any third party, or (iv) providing an unlawful personal gain or benefit, of financial or other value, to such Government Official(s); or (b) otherwise for the benefit of Licensee, or any of its Affiliates, in each case of (a) and (b), in violation of any federal, state, local, municipal, foreign, international, multinational or other administrative law. As used herein, “**Government Official**” means: (A) any elected or appointed government official (e.g., a member of a ministry of health), (B) any employee or person acting for or on behalf of a government official, agency, or enterprise performing a governmental function, (C) any political party officer, employee, or person acting for or on behalf of a political party or candidate for public office, (D) an employee or person acting for or on behalf of a public international organization, or (E) any person otherwise categorized as a government official under local law. As used in this Section 10.4, “government” is meant to include all levels and subdivisions of non-U.S. governments (i.e., local, regional, or national and administrative, legislative, or executive).

10.5. No Action Required Which Would Violate Law. In no event shall either Party be obligated under this Agreement to take any action or omit to take any action that such party believes, in good faith, would cause such Party to violate any Applicable Law, including without limitation the Compliance Laws.

10.6. No Other Warranties. EXCEPT AS EXPRESSLY STATED IN THIS SECTION 10, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE, INCLUDING BUT NOT LIMITED TO WARRANTIES OF TITLE, NON-INFRINGEMENT, VALIDITY, ENFORCEABILITY, MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. EXCEPT AS EXPRESSLY STATED IN THIS SECTION 10, ANY INFORMATION OR MATERIALS PROVIDED BY PFIZER OR ITS AFFILIATES IS MADE AVAILABLE ON AN “AS IS” BASIS WITHOUT WARRANTY WITH RESPECT TO COMPLETENESS, COMPLIANCE WITH REGULATORY

STANDARDS OR REGULATIONS OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER KIND OF WARRANTY WHETHER EXPRESS OR IMPLIED.

11. INDEMNIFICATION.

11.1. Indemnification by Licensee. Licensee agrees to indemnify, hold harmless and defend Pfizer and its Affiliates, and its and their respective officers, directors, employees, contractors, agents and assigns (collectively, “**Pfizer Indemnitees**”), from and against any Claims arising or resulting from: (a) the Development of a Product by Licensee, its Affiliates, subcontractors or sublicensees, (b) the Commercialization of a Product by Licensee, its Affiliates, subcontractors or sublicensees, (c) the negligence, recklessness or wrongful intentional acts or omissions of Licensee, its Affiliates, subcontractors or sublicensees in connection with the exercise of rights under this Agreement, (d) breach by Licensee of any representation, warranty or covenant as set forth in this Agreement, (e) breach by Licensee of the scope of the license set forth in Section 2.1, or (f) the supply of Compounds or Products in accordance with Section 4.9 hereof, except, in each instance, to the extent that such Claim arose or resulted from the fraudulent conduct, gross negligence or willful misconduct by any Pfizer Indemnitee. As used herein, “**Claims**” means collectively, any and all Third Party demands, claims, actions and proceedings (whether criminal or civil, in contract, tort or otherwise) for losses, damages, liabilities, costs and expenses (including reasonable attorneys’ fees) sought by the relevant Third Party in connection with such demand, claim, action or proceeding or incurred by the relevant Pfizer Indemnitee.

11.2. Indemnification Procedure. In connection with any Claim for which a Pfizer Indemnitee seeks indemnification from Licensee pursuant to this Agreement, Pfizer shall: (a) give Licensee prompt written notice of the Claim; *provided, however,* that failure to provide such notice shall not relieve Licensee from its liability or obligation hereunder, except to the extent of any material prejudice as a direct result of such failure; (b) cooperate with Licensee, at Licensee’s expense, in connection with the defense and settlement of the Claim; and (c) permit Licensee to control the defense and settlement of the Claim; *provided, however,* that Licensee may not settle the Claim without Pfizer’s prior written consent, such consent not be unreasonably withheld, conditioned or delayed, in the event that such settlement materially adversely impacts Pfizer’s rights or obligations. Further, Pfizer shall have the right to participate (but not control) and be represented in any suit or action by advisory counsel of its selection and at its own expense.

12. LIMITATION OF LIABILITY.

12.1. Consequential Damages Waiver. EXCEPT FOR A BREACH OF SECTION 9 OR FOR OBLIGATIONS ARISING UNDER SECTION 11, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR ANY INDIRECT, CONSEQUENTIAL, SPECIAL, EXEMPLARY OR PUNITIVE DAMAGES, INCLUDING DAMAGES FOR LOST PROFITS OR LOST REVENUES REGARDLESS OF WHETHER IT HAS BEEN INFORMED OF THE POSSIBILITY OR LIKELIHOOD OF SUCH DAMAGES OR THE TYPE OF CLAIM, CONTRACT OR TORT (INCLUDING NEGLIGENCE).

12.2. Liability Cap. EXCEPT FOR A BREACH OF SECTION 9 OR FOR OBLIGATIONS ARISING UNDER SECTION 11, IN NO EVENT SHALL PFIZER’S LIABILITY FOR DAMAGES IN CONNECTION WITH THIS AGREEMENT EXCEED THE CAP, REGARDLESS OF WHETHER PFIZER HAS BEEN INFORMED OF THE POSSIBILITY OR LIKELIHOOD OF SUCH DAMAGES OR THE TYPE OF CLAIM, CONTRACT OR TORT (INCLUDING NEGLIGENCE). “**Cap**” means the total Fees paid by Licensee to Pfizer during the [***] immediately preceding the event giving rise to the claim. As used herein, “**Fees**” means collectively, the Upfront Payment and any and all Milestone Payments, Royalties and Sublicensing Income.

13. TERM; TERMINATION.

13.1. Term. The term of this Agreement (“**Term**”) shall commence as of the Effective Date and shall expire upon the last-to-expire Royalty Term, unless earlier terminated as provided herein. Upon expiration of the Royalty Term with respect to a Product in a country, the licenses granted to Licensee under this Agreement shall convert to perpetual, irrevocable, non-exclusive, fully paid up, non-royalty-bearing licenses with respect to such Product in such country and no other amounts shall be due by Licensee with respect to such Product in such country hereunder.

13.2. Termination for Cause. Each Party shall have the right, without prejudice to any other remedies available to it at law or in equity, to terminate this Agreement in the event the other Party materially breaches any of its obligations hereunder and fails to cure such breach within [***] of receiving notice describing such breach; *provided, however*, if such breach is capable of being cured, but cannot be cured within such [***] period, and the breaching Party initiates actions to cure such breach within such period and thereafter diligently pursues such actions, the breaching Party shall have such additional period as is reasonable to cure such breach, but in no event will such additional period exceed [***]. All timeframes in this Section 13.2 shall be tolled until the resolution pursuant to Section 16 of any good faith dispute over the existence or nature of the breach, or over the adequacy of the cure thereof. Any termination by a Party under this Section 13.2 shall be without prejudice to any damages or other legal or equitable remedies to which it may be entitled from the other Party. For the avoidance of doubt, Licensee's failure to use Commercially Reasonable Efforts to Develop and Commercialize the Product or failure to make an undisputed Milestone Payment or Royalty payment shall constitute a material breach by Licensee under this Agreement. Without limiting the foregoing, if Pfizer at any time determines that Licensee may have breached any of the representations or warranties in Section 10.4 of this Agreement or otherwise failed to meet its obligations under Section 10.4 of this Agreement, then Pfizer (a) shall request a meeting with Licensee to discuss such matter, (b) shall consider in good faith all information provided by Licensee with respect to such matter and (c) may terminate this Agreement immediately upon written notice to Licensee if (i) Licensee does not meet with Pfizer within [***] of such request or (ii) after complying with the foregoing (a) and (b) Pfizer concludes, in its sole discretion, that Licensee breached any of the representations or warranties in Section 10.4 of this Agreement or otherwise failed to meet its obligations under Section 10.4 of this Agreement.

13.3. Termination for a Bankruptcy Event. Each Party shall have the right to terminate this Agreement in the event of a Bankruptcy Event with respect to the other Party. "**Bankruptcy Event**" means the occurrence of any of the following: (a) the institution of any bankruptcy, receivership, insolvency, reorganization or other similar proceedings by or against a Party under any bankruptcy, insolvency, or other similar law now or hereinafter in effect, including any section or chapter of the United States Bankruptcy Code, as amended or under any similar laws or statutes of the United States or any state thereof (the "**Bankruptcy Code**"), where in the case of involuntary proceedings such proceedings have not been dismissed or discharged within [***] after they are instituted, (b) the insolvency or making of an assignment for the benefit of creditors or the admittance by a Party of any involuntary debts as they mature, (c) the institution of any reorganization, arrangement or other readjustment of debt plan of a Party not involving the Bankruptcy Code, (d) appointment of a receiver for all or substantially all of a Party's assets, or (e) any corporate action taken by the board of directors of a Party in furtherance of any of the foregoing actions.

13.4. Termination for Convenience. For the period from the Effective Date until the first Regulatory Approval of the first Product in any country in the Territory, Licensee shall have the right to terminate this Agreement for convenience upon [***] prior written notice to Pfizer. Upon such receipt of the first Regulatory Approval of the Product and continuing through the end of the Term, Licensee shall have the right to terminate this Agreement for convenience upon [***] prior written notice to Pfizer.

13.5. Effects of Termination.

13.5.1. Termination by Licensee for Cause or Bankruptcy Event. In the event that Licensee terminates this Agreement pursuant to Section 13.2, Section 13.3 or Section 17.4, the following shall apply:

- (a) **Rights and Obligations.** Except as otherwise provided herein, all rights and obligations of each Party hereunder shall cease, including, subject to Section 13.5.1(b), the licenses granted to Licensee pursuant to Section 2.1.
- (b) **Licensee Inventory.** Licensee, its Affiliates and sublicensees shall have the right to sell its remaining inventory of Product so long as Licensee has fully paid, and continues to pay when due, all Royalties,

Milestone Payments and Sublicensing Income payments owed to Pfizer, and Licensee is otherwise not in material breach of this Agreement.

13.5.2. Termination by Pfizer for Cause, Bankruptcy Event; Termination by Licensee for Convenience. In the event that Pfizer terminates this Agreement pursuant to Section 13.2, Section 13.3, or Licensee terminates this Agreement pursuant to Section 13.4, the following shall apply:

- (a) **Rights and Obligations.** Except as otherwise provided herein, all rights and obligations of each Party hereunder shall cease.
- (b) **Licenses.** Pfizer shall have a perpetual, irrevocable, worldwide, fully-paid up, royalty-free exclusive right and license, with the right to grant sublicenses, under the Developed IP that is Controlled by Licensee and was or is then being used in the Research, Development, Manufacture or Commercialization of a Compound or Product, as such Developed IP exists as of the effective date of termination, to use, Develop, Commercialize, Manufacture and exploit Compounds and Products.
- (c) **Transition.** During the notice period provided in Section 13.2 or Section 13.4, as applicable to such termination, or as soon as practicable upon notice of termination pursuant to Section 13.3, at Pfizer's sole option, Pfizer shall prepare and the Parties shall negotiate a transition plan that will include, at a minimum, a plan for accomplishing the activities described in this Section 13.5.2(c).

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- (i) **Continued Development.** At Pfizer's request and expense, Licensee shall continue on-going Development for a mutually agreed-upon period following termination of this Agreement, which period shall not be [***] unless otherwise agreed to by the Parties; provided that in no event shall Licensee be required to continue such Development if Licensee has a reasonable safety or ethical concern with respect thereto or such Development would violate Applicable Law. For avoidance of doubt, if Pfizer chooses not to continue a Clinical Trial initiated by Licensee or if, for the safety of any subject as determined at the time of termination, any Clinical Trial with respect to a Product should not be continued, Licensee shall be solely responsible for the cost of winding down such trial, including compliance with any ethical or other requirements imposed by an applicable Regulatory Authority.
- (ii) **Technology Transfer.** At Pfizer's request, Licensee shall make available to Pfizer all currently available records and data Controlled by Licensee that exist as of the effective date of termination that are related to the Development, Manufacture or Commercialization of a Compound or Product, and that are necessary or useful for Pfizer to continue using, Developing, Commercializing and Manufacturing the Product.
- (iii) **Regulatory Matters.** At Pfizer's request, Licensee shall transfer and assign to Pfizer (or its designee) all Regulatory Approvals, pricing approvals and Regulatory Filings held by Licensee with respect to the Product, provided that if such transfer and assignment is not permitted by the applicable Regulatory Authority, Licensee shall permit Pfizer to cross-reference and rely upon such Regulatory Approvals, pricing approvals and Regulatory Filings. Licensee shall make available to Pfizer copies of all regulatory documentation and records related to the Product, including information contained in the regulatory and safety databases. The Parties shall cooperate to ensure the prompt transition of regulatory responsibilities for the Product from Licensee to Pfizer.

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- (iv) **Trademarks.** Pfizer shall have an exclusive, fully paid-up, royalty-free, worldwide, transferable, sublicensable, perpetual and irrevocable license to use the trademarks existing at the time of termination Controlled by Licensee and used in connection with Commercializing a Product at the time

of termination that are solely associated with a Product (and such license will extend to names or logos associated with Licensee itself only in the event a Regulatory Authority requires such use to indicate manufacturing source or other identifying information with the respect to the inventory described in the following Section 13.5.2(c)(v) in each case, solely for the purpose of Commercializing the relevant Product. Pfizer shall have a transitional license to use Licensee's trademarks and promotional materials solely for the purpose of using, Developing, Commercializing and Manufacturing the Product.

- (v) **Inventory and Supply.** At Pfizer's request, Licensee shall transfer to Pfizer (or its designee) all Product and all components and in-process inventory with respect thereto produced or held by Licensee as of the effective date of termination with respect to the Manufacture of Product, except as necessary to perform its obligations under Section 13.5.2(c)(i). At Pfizer's request, (A) if Licensee is using a CMO to Manufacture the Product, Licensee shall, if possible, promptly assign the relevant CMO agreement to Pfizer, or (B) if not, Licensee shall continue to Manufacture or have Manufactured the Product for a period of not less [***], including, at Pfizer's request, a reasonable stock build. Pfizer shall pay to Licensee the actual cost of Manufacturing associated with inventory and Product received by Pfizer pursuant to this Section 13.5.2(c)(v).
- (vi) **Third Party Agreements.** At Pfizer's request, to the extent Licensee is able to do so, Licensee shall assign to Pfizer (or its designee) any agreements with Third Parties with respect to the Development, Commercialization, Manufacture and exploitation of a Product. With respect to Third Party agreements that Licensee is not able to assign to Pfizer, Licensee shall cooperate to give Pfizer the benefit of such contracts for a reasonable transitional period.

- (d) **Licensee Inventory.** In the event that Licensee terminates this Agreement pursuant to Section 13.4 and Pfizer elects not to initiate transition activities pursuant to Section 13.5.2(c) prior to the effective date of such termination, Licensee shall have the right to sell its remaining inventory of Product so long as Licensee has fully paid, and continues to pay when due, all Royalties, Sublicensing Income payments or Transaction Completion and Milestone Payments owed to Pfizer, and Licensee is otherwise not in material breach of this Agreement; provided, however, that in no event shall Licensee be required to assign any such agreement absent a release from all liabilities and obligations arising thereunder through the action or inaction of Pfizer following such assignment.
- (e) **Sublicenses.** Any existing agreements that contain a sublicense under the Licensed Technology shall terminate

13.6. Survival. Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing hereunder prior to such expiration or termination. Without limiting the foregoing, the provisions of Sections 1, 6, 7.1, 9, 10.6 11, 12, 13.1, 13.5, 13.6, 15, 16, 17.3 17.8, and 17.14 shall survive expiration or termination of this Agreement.

13.7. Rights in Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by Pfizer are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that Licensee, as licensee of certain rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against Pfizer under the U.S. Bankruptcy Code, Licensee shall be entitled to a complete duplicate of (or complete access to, as appropriate) any intellectual property licensed to Licensee and all embodiments of such intellectual property, which, if not already in Licensee's possession, shall be promptly delivered to it (a) upon any such commencement of a bankruptcy proceeding upon Licensee's written request therefor, unless Pfizer elects to continue to perform all of its obligations under this Agreement or (b) if not delivered under clause (a), following the rejection of this Agreement by Pfizer upon written request therefor by Licensee. This Section 13.7 shall apply ex-US *mutatis mutandis*.

14. PUBLICITY; PUBLICATIONS.

14.1. Use of Names. Subject to Pfizer’s rights pursuant to Section 13.5.2(c)(iv) and except as required to comply with Applicable Law, neither Party (nor any of its Affiliates or agents) shall use the registered or unregistered trademarks, service marks, trade dress, trade names, logos, insignia, domain names, symbols or designs of the other Party or its Affiliates in any press release, publication or other form of promotional disclosure without the prior written consent of the other Party in each instance; provided, however, that Licensee, and any of its Affiliates or sublicensees, may state publicly that Licensee has received, or been sublicensed under, a license from Pfizer to use, Develop, Manufacture, Commercialize or exploit the Compound or Product.

14.2. Press Releases. The Parties acknowledge that one or both Parties, either singly or jointly, may desire to publish one or more press releases relating to this Agreement and the rights granted hereunder. However, except as permitted by Section 9 or 14.3, each Party agrees not to issue any press release or other public statement, whether written, electronic, oral or otherwise, disclosing the existence of this Agreement, the terms hereof or any information relating to this Agreement without the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed. Neither Party will be prevented from complying with any duty of disclosure it may have pursuant to Applicable Law or the rules of any recognized stock exchange so long as the Disclosing Party provides the other Party at least [***] prior written notice to the extent practicable and only discloses information to the extent required by Applicable Law or the rules of any recognized stock exchange.

14.3. Publications.

14.3.1. During the Term, Pfizer and its Affiliates may, subject to the prior written consent of Licensee (in its sole discretion), publish or present any results and information initially submitted for publication or presentation prior to the Effective Date; provided that Pfizer will not be required to seek Purchaser’s prior written approval to publish or present the publications set forth on Schedule 14.3. Pfizer and its Affiliates will not publish or present any results and information that were not initially submitted for publication or presentation prior to the Effective Date, without the prior written consent of Licensee (in its sole discretion). Third Parties performing investigator sponsored research activities using the Compound or Product may publish the results and information related to their work without the prior written approval of Licensee.

14.3.2. During the Term, Licensee shall submit to Pfizer for review and approval the portion of any proposed publication or public presentation that contains Pfizer’s Confidential Information, other than any pre-clinical or clinical data contained in Licensed Know-How (the “**Review Material**”). A written copy of the Review Material shall be submitted to Pfizer no later than [***] before submission for publication or presentation. Pfizer shall provide its comments with respect to the Review Material within [***] of its receipt of such written copy. Pfizer shall not have a review or approval right with respect to any publication or public presentation by or on behalf of Licensee of any pre-clinical or clinical data contained in the Licensed Know-How.

15. LICENSEE INSURANCE.

15.1. Insurance Requirements. Licensee will maintain during the Term and until the later of: (a) [***] after termination or expiration of this Agreement, or (b) the date that all statutes of limitation covering claims or suits that may be instituted for personal injury based on the sale or use of any Product have expired, commercial general liability insurance from a minimum “A-” AM Best rated insurance company, including contractual liability and product liability or clinical trials, if applicable [***]. Licensee has the right to provide the total limits required by any combination of primary and umbrella/excess coverage. The minimum level of insurance set forth herein shall not be construed to create a limit on Licensee’s liability hereunder. Such policies shall name Pfizer and its Affiliates as additional insured and provide a waiver of subrogation in favor of Pfizer and its Affiliates. Such insurance policies shall be primary and non-contributing with respect to any other similar insurance policies available to Pfizer or its Affiliates. Any deductibles for such insurance shall be assumed by Licensee.

15.2. Policy Notification. Licensee shall provide Pfizer with certified copies of such policies or original certificates of insurance evidencing such insurance: (a) prior to execution by both Parties of this Agreement, and (b) prior to expiration of any one coverage. Licensee shall provide that Pfizer shall be given at least [***] written notice prior to cancellation, termination or any material change to restrict the coverage or reduce the limits afforded.

16. DISPUTE RESOLUTION.

16.1. Arbitration.

16.1.1.General. Any disputes, controversies or other claims arising out of this Agreement, its interpretation, validity, performance, enforceability, breach or termination (“**Disputes**”) that are not settled amicably shall be referred by sending written notice of the Dispute to the other Party for final and binding arbitration with the office of the American Arbitration Association in New York County, New York in accordance with the then-prevailing commercial arbitration rules of the American Arbitration Association.

16.1.2.Number of Arbitrators. Each Party shall appoint one (1) arbitrator who is neutral to the Parties, and the Party-appointed arbitrators shall jointly appoint a third arbitrator who is also neutral to the Parties.

16.1.3.Powers of the Arbitrators.

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- (a) The arbitrators are authorized to award to the prevailing Party, if a prevailing party is determined by the arbitrators, such Party’s costs and expenses, including attorneys’ fees.
 - (b) The arbitrators may not award punitive, exemplary, or consequential damages that are prohibited by this Agreement, nor may the arbitrators apply any multiplier to any award of actual damages, except as may be required by statute.
 - (c) The arbitrators shall have the discretion to hear and determine at any stage of the arbitration any issue asserted by any Party to be dispositive of any claim or counterclaim, in whole or part, in accordance with such procedure as the arbitrators may deem appropriate, and the arbitrators may render an award on such issue.
 - (d) In addition to the authority conferred on the arbitrators by the rules designated in this Agreement, and without prejudice to any provisional measures that may be available from a court of competent jurisdiction, the arbitrators shall have the power to grant any provisional measures that the arbitrators deems appropriate, including but not limited to provisional injunctive relief, and any provisional measures ordered by the arbitrators may, to the extent permitted by Applicable Law, be deemed to be a final award on the subject matter of the measures and shall be enforceable as such
 - (e) All decisions of the arbitrators shall be made by a majority of the arbitrators.

16.1.4.Confidentiality. No information concerning an arbitration, beyond the names of the parties and the relief requested, may be unilaterally disclosed to a Third Party by any Party unless required by Applicable Law. Any documentary or other evidence given by a Party or witness in the arbitration shall be treated as confidential by any Party whose access to such evidence arises exclusively as a result of its participation in the arbitration, and shall not be disclosed to any Third Party (other than a witness or expert), except as may be required by Applicable Law.

16.2.No Trial By Jury. THE PARTIES EXPRESSLY WAIVE AND FOREGO ANY RIGHT TO TRIAL BY JURY.

17. GENERAL PROVISIONS.

17.1. Assignment. Neither Party may assign its rights and obligations under this Agreement without the other Party's prior written consent, except that: (a) Pfizer may assign to a Third Party its rights to receive some or all of the payments payable hereunder, (b) each Party may assign its rights and obligations under this Agreement or any part hereof to one or more of its Affiliates without the consent of the other Party; and (c) either Party may assign this Agreement to an acquirer of such Party in the event of a Change of Control of such Party. The assigning Party shall provide the other Party with prompt written notice of any such assignment. Any permitted assignee pursuant to clauses (b) and (c) above shall assume all obligations of its assignor under this Agreement, and no permitted assignment shall relieve the assignor of liability for its obligations hereunder. Any attempted assignment in contravention of the foregoing shall be void.

17.2. Severability. Should one or more of the provisions of this Agreement become void or unenforceable as a matter of law, then such provision will be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement, and the Parties agree to substitute a valid and enforceable provision therefor which, as nearly as possible, achieves the desired economic effect and mutual understanding of the Parties under this Agreement.

17.3. Governing Law. This Agreement shall be governed by and construed under the laws in effect in the State of New York, U.S. without giving effect to any conflicts of laws provision thereof or of any other jurisdiction that would produce a contrary result. Section 16 does not intend to deprive any New York court of competent jurisdiction with respect to its power to issue a pre-arbitral injunction, pre-arbitral attachment or other order in aid of arbitration proceedings or the enforcement of any judgment or award. In any such action, the courts of New York shall have exclusive jurisdiction over any action brought to enforce this Agreement, and each of the Parties hereto irrevocably: (a) submits to such exclusive jurisdiction for such purpose; (b) waives any objection which it may have at any time to the laying of venue of any proceedings brought in such courts; (c) waives any claim that such proceedings have been brought in an inconvenient forum, (d) further waives the right to object with respect to such proceedings that any such court does not have jurisdiction over such Party, and (e) consents to service of process in the manner provided by Section 17.8 or by first class certified mail, return receipt requested, postage prepaid.

17.4. Force Majeure. Except with respect to delays or nonperformance caused by the negligent or intentional act or omission of a Party, any delay or nonperformance by such Party (other than payment obligations under this Agreement) will not be considered a breach of this Agreement to the extent such delay or nonperformance is caused by acts of God, natural disasters, acts of the government or civil or military authority, fire, floods, epidemics, pandemics, quarantine, energy crises, war or riots or other similar cause outside of the reasonable control of such Party (each, a "**Force Majeure Event**"), *provided* that the Party affected by such Force Majeure Event will promptly begin or resume performance as soon as reasonably practicable after the event has abated. If the Force Majeure Event prevents a Party from performing any of its obligations under this Agreement for [***] or more, then the other Party may terminate this Agreement immediately upon written notice to the non-performing Party.

17.5. Waivers and Amendments. The failure of any Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other Party. No waiver shall be effective unless it has been given in writing and signed by the Party giving such waiver. No provision of this Agreement may be amended or modified other than by a written document signed by authorized representatives of each Party.

17.6. Relationship of the Parties. Nothing contained in this Agreement shall be deemed to constitute a partnership, joint venture, or legal entity of any type between Pfizer and Licensee, or to constitute one Party as the agent of the other. Moreover, each Party agrees not to construe this Agreement, or any of the transactions contemplated hereby, as a partnership for any tax purposes. Each Party shall act solely as an independent contractor, and nothing in this Agreement shall be construed to give any Party the power or authority to act for, bind, or commit the other Party.

17.7. Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns.

17.8. Notices. All notices, consents, waivers, and other communications under this Agreement must be in writing and will be deemed to have been duly given when: (a) delivered by hand (with written confirmation of receipt), (b) sent by fax (with written confirmation of receipt), *provided* that a copy is sent by an internationally recognized overnight delivery service (receipt requested), (c) sent by email (with confirmation of receipt) or (d) when received by the addressee, if sent by an internationally recognized overnight delivery service (receipt requested), in each case to the appropriate addresses and fax numbers set forth below (or to such other addresses and fax numbers as a Party may designate by written notice):

If to Pfizer:

Pfizer Inc.
235 East 42nd Street
New York, NY 10017
Attention: General Counsel

If to Licensee:

Celcuity Inc.
16305 36th Avenue North, Suite 100
Minneapolis, MN 55446
Fax: 763-226-2314
Email: [Omitted]
Attention: Brian Sullivan, CEO

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17.9. Further Assurances. Licensee and Pfizer hereby covenant and agree without the necessity of any further consideration, to execute, acknowledge and deliver any and all such other documents and take any such other action as may be reasonably necessary or appropriate to carry out the intent and purposes of this Agreement.

17.10.No Third Party Beneficiary Rights. This Agreement is not intended to and shall not be construed to give any Third Party any interest or rights (including, without limitation, any third party beneficiary rights) with respect to or in connection with any agreement or provision contained herein or contemplated hereby.

17.11.Entire Agreement; Confidentiality Agreement.

17.11.1. This Agreement, together with its Schedules, sets forth the entire agreement and understanding of the Parties as to the subject matter hereof and supersedes all proposals, oral or written, and all other prior communications between the Parties with respect to such subject matter, including, without limitation, that certain Confidentiality Agreement by and between the Parties [***]. The Parties acknowledge and agree that, as of the Effective Date, all Confidential Information (as defined in the CDA) disclosed by Pfizer or its Affiliates pursuant to the CDA shall be considered Pfizer's Confidential Information and subject to the terms set forth in this Agreement.

17.11.2. In the event of any conflict between a material provision of this Agreement and any Schedule hereto, the Agreement shall control.

17.12.Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

17.13.Cumulative Remedies. No remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.

17.14. Waiver of Rule of Construction. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, any rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

[Signature page to follow]

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IN WITNESS WHEREOF, the Parties intending to be bound have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

CELCUITY INC.

By: /s/ Brian Sullivan

Name: Brian Sullivan

Title: Chairman and CEO

PFIZER INC.

By: /s/ Jeff Settleman

Name: Jeff Settleman

Title: Senior Vice President & Chief Scientific Officer, Pfizer Oncology R&D

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SCHEDULE 1.19: COMPOUND

[INTENTIONALLY OMITTED]

43

SCHEDULE 1.46: KNOWLEDGE

[INTENTIONALLY OMITTED]

44

SCHEDULE 1.47: LICENSED KNOW-HOW

[INTENTIONALLY OMITTED]

45

SCHEDULE 1.48: LICENSED PATENT RIGHTS

[INTENTIONALLY OMITTED]

46

SCHEDULE 3: TRANSFER ACTIVITIES

[INTENTIONALLY OMITTED]

SCHEDULE 4.7: DEVELOPMENT PLAN

[INTENTIONALLY OMITTED]

SCHEDULE 10.2: CLAIMS

[INTENTIONALLY OMITTED]

SECOND AMENDMENT TO LEASE

This Second Amendment to Lease (“Amendment”), dated this 19 day of July, 2021, is by and between **West Glen Development I, LLC**, a Minnesota limited liability company (“Landlord”) and **Celcuity, Inc.**, a Delaware corporation (“Tenant”), and amends that certain Commercial Lease agreement dated the 28th day of September, 2017, and amended by that certain First Amendment to Lease dated July 28, 2020 (together the Commercial Lease and First Amendment shall be referred to as the “**Lease Agreement**”) by and between Landlord and Tenant with respect to that certain building located at 16305 – 36th Avenue North, the City of Plymouth, Hennepin County, Minnesota. Unless otherwise indicated, the terms defined in the Lease Agreement shall have the same meanings when used herein.

WHEREAS, the parties agreed to extend the Term of the Lease Agreement pursuant to Section 45 of the Lease Agreement, except for the Base Rent adjustment as provided herein.

NOW, THEREFORE, in consideration of the foregoing, the parties hereby agree that:

1. **TERM.** The Term of the Lease will be extended for one (1) year to terminate on April 30, 2023, unless sooner terminated in accordance with the provisions of the Lease Agreement.

2. **BASE RENT.** The monthly installments of Base Rent payable for the Premises during the Term are as follows:

Months	Price Per Square Foot	Monthly
May 1, 2022- April 30, 2023	\$12.52	\$17,019.89

3. **SECTION 45 OF LEASE AGREEMENT.** Section 45 of the Lease Agreement, Option to Extend Term, shall be deleted and replaced with the following:

A. Subject to the provisions of Article 45B below and provided this Lease Agreement or Tenant’s right of possession hereunder has not been earlier terminated, Tenant shall have the right to extend the Term of the Lease Agreement as to all, but not less than all, of the Premises then being leased hereunder, for one additional period of one (1) year beginning immediately following the end of the Term (the “**Extended Term**”) subject to the following terms and conditions:

- (i) Tenant shall give written notice to Landlord of the exercise of Tenant’s right to extend the Term of this Lease Agreement no later than nine (9) months prior to the commencement of the Extended Term, time being of the essence (the “**Renewal Notice**”). If no such Renewal Notice is timely given, this Lease Agreement shall terminate as of the end of the initial Term;
- (ii) Tenant shall not be in default under this Lease Agreement beyond the passage of any applicable period of cure, grace or notice at the time of giving the Renewal Notice or at any time thereafter to and including the commencement of the Extended Term; and
- (iii) The extension of the Term hereunder for the Extended Term shall be on the same terms and conditions as are applicable to the initial Term;

provided, however, (i) Tenant shall have no further right to extend the Term of this Lease Agreement, and (ii) the Base Rent payable by Tenant to Landlord in monthly installments during the Extended Term shall be as follows:

Months	Price Per Square Foot	Monthly
May 1, 2023 to April 30, 2024	\$12.77	\$17,359.75

B. It is acknowledged and agreed by the parties that the right of Tenant (hereafter the “**Original Tenant**”) to extend the Term of this Lease Agreement under Article 45A above is personal to Original Tenant. and should said Original Tenant either assign this Lease Agreement or sublet all or any part of the Premises to any person or entity other than to an Affiliate of said Original Tenant, Article 45A above shall automatically become null and void and of no further force or effect.

4. **POSSESSION.** Tenant acknowledges and agrees that the Premises and Tenant Improvements have been delivered to Tenant by Landlord in the condition required by the Lease Agreement and Tenant has accepted possession of the Premises in such condition.

5. **“AS IS.”** Tenant accepts the Premises as is, where is, and without any warranty or representation, express or implied, or arising by operation of law, including, but in no way limited to, any warranty of quantity, quality, condition, habitability, merchantability, suitability or fitness for a particular purpose.

6. **Brokerage.** With regard to Section 41 of the Lease, each of the parties represents and warrants that there are no Leasing Commissions due in connection with this Amendment, and agrees to indemnify the other party against, and hold it harmless from all liabilities arising from any claim for Leasing Commissions asserted by a broker, agent or other person or entity claiming through the indemnifying party, including without limitation, reasonable attorneys fees incurred in connection therewith.

Except as otherwise stated herein, all of the remaining terms and conditions of the Lease Agreement shall continue to be unchanged, in full force and effect.

Landlord: West Glen Development I, LLC
A Minnesota limited liability company

Date: July 22, 2021 By: /s/ Mark Shulstad, Attorney in Fact for Brad
Moen
Bradley L. Moen, Vice President

Date: July 22, 2021 By: /s/ Michael J. Leuer
Michael J. Leuer, Governor

Tenant: Celcuity, Inc.
A Delaware corporation

Date: July 19, 2021 By: /s/ Brian F. Sullivan
Name: Brian F. Sullivan
Its: Chief Executive Officer

**Amendment No. 1 to
License Agreement
("Amendment No. 1")**

Date: May 6, 2021

Name of Original Agreement: License Agreement (the "Agreement")

Effective Date of Original Agreement: April 8, 2021

Parties: Pfizer Inc. ("Pfizer") and Celcuity Inc. ("Licensee")

WHEREAS, the Parties hereto desire to amend, among other things, certain terms of the Agreement.

NOW, THEREFORE, in order to accommodate the desired amendment(s), the Parties hereby agree as follows:

1. Defined Terms. Capitalized terms used but not defined herein shall have the respective meanings ascribed to such terms in the Agreement.
2. Amendment(s) to the Agreement.

- 2.1. Section 4.8 of the Agreement is hereby revised to read, in its entirety, as follows:

"4.8. [*] supply.** Pfizer agrees to supply [***] to Licensee (but not to a sublicensee or assignee of Licensee) [***]."

- 2.2. Section 5.3 of the Agreement is hereby revised to read, in its entirety, as follows:

"5.3 [*] Milestone Payments.** In consideration of the licenses and rights granted to Licensee hereunder, Licensee shall pay to Pfizer the amounts set forth below within sixty (60) days following the first achievement of each event described below for the applicable Product (each event, a "[***] Milestone" and each payment, a "[***] Milestone Payment")."

[***] MILESTONE	[***] MILESTONE PAYMENT
(1) [***]	[***]
(2) [***]	[***]
(3) [***]	[***]
(4) [***]	[***]
(5) [***]	[***]
(6) [***]	[***]
(7) [***]	[***]
(8) [***]	[***]
(9) [***]	[***]

Page 1 of 4

The total amount of [***] Milestone Payments shall not exceed [***]. For the avoidance of doubt: (i) each [***] Milestone Payment shall be payable only once upon the first achievement of the applicable [***] Milestone regardless of the number of Products that achieve such [***] Milestone; and (ii) satisfaction of a [***] Milestone by a sublicensee or assignee of, or Third Party retained by, Licensee or its Affiliates shall be deemed to have been satisfied by Licensee for purposes of this Section 5.3. A Product that achieves (A) [***] Milestone (2) cannot be the same Product that achieves [***] Milestone (6); (B) [***] Milestone (3) cannot be the same Product that achieves [***] Milestone (7); (C) [***] Milestone (4) cannot be the same Product that achieves [***] Milestone (8); and (D) [***] Milestone (5) cannot be the same Product that achieves [***] Milestone (9).

If a [***] Milestone is achieved without achieving a [***] Milestone that would otherwise have occurred prior to the [***] Milestone that was achieved, then all prior [***] Milestones shall be deemed to have been achieved, and if not previously paid, the corresponding [***] Milestone Payments shall become payable."

- 2.3. Schedule 4.7 of the Agreement is hereby replaced in its entirety with Schedule 4.7 attached hereto.

3. Ratification of the Agreement. Except as expressly set forth in Article 2 above, the Agreement shall remain unmodified and in full force and effect. The execution, delivery and effectiveness of this Amendment No. 1 shall not, except as expressly provided herein, operate as a waiver of any right, power or remedy of the parties to the Agreement, nor constitute a waiver of any provision of the Agreement.
4. Counterparts. This Amendment No. 1 may be executed in any number of counterparts, each of which shall be an original instrument and all of which, when taken together, shall constitute one and the same agreement.

IN WITNESS WHEREOF, the duly authorized representatives of Pfizer and Licensee have executed this Amendment No. 1 as of the date first above written.

Celucuity Inc.

Pfizer Inc.

By: /s/ Brian Sullivan
Print Brian
Name: Sullivan
Title: CEO
(Duly authorized)

By: /s/ John DeYoung
Print John
Name: DeYoung
Title: Vice President
(Duly authorized)

**SCHEDULE 4.7
DEVELOPMENT PLAN**

[INTENTIONALLY OMITTED]

CERTIFICATION UNDER SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Brian F. Sullivan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Celcuity 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.

Dated: August 11, 2021

By /s/ Brian F. Sullivan

Brian F. Sullivan
Chairman and Chief Executive Officer

CERTIFICATION UNDER SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Vicky Hahne, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Celcuity 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.

Dated: August 11, 2021

By /s/ Vicky Hahne

Vicky Hahne
Chief 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 filing of the Quarterly Report on Form 10-Q for the quarter ended June 30, 2021 (the “Report”) by Celcuity Inc. (“Registrant”), I, Brian F. Sullivan, the Chief Executive Officer of the Company, certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that to the best of my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Dated: August 11, 2021

By /s/ Brian F. Sullivan
Brian F. Sullivan
Chairman and Chief Executive 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 filing of the Quarterly Report on Form 10-Q for the quarter ended June 30, 2021 (the “Report”) by Celcuity Inc. (“Registrant”), I, Vicky Hahne, the Chief Financial Officer of the Company, certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that to the best of my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Dated: August 11, 2021

By /s/ Vicky Hahne

Vicky Hahne
Chief Financial Officer

Cover - shares

6 Months Ended
Jun. 30, 2021

Aug. 02, 2021

Cover [Abstract]

<u>Entity Registrant Name</u>	CELCUITY INC.	
<u>Entity Central Index Key</u>	0001603454	
<u>Document Type</u>	10-Q	
<u>Amendment Flag</u>	false	
<u>Current Fiscal Year End Date</u>	--12-31	
<u>Entity Small Business</u>	true	
<u>Entity Shell Company</u>	false	
<u>Entity Emerging Growth Company</u>	true	
<u>Entity Current Reporting Status</u>	Yes	
<u>Document Period End Date</u>	Jun. 30, 2021	
<u>Entity Filer Category</u>	Non-accelerated Filer	
<u>Document Fiscal Period Focus</u>	Q2	
<u>Document Fiscal Year Focus</u>	2021	
<u>Entity Ex Transition Period</u>	true	
<u>Entity Common Stock Shares Outstanding</u>		14,904,898
<u>Document Quarterly Report</u>	true	
<u>Document Transition Report</u>	false	
<u>Entity File Number</u>	001-38207	
<u>Entity Incorporation State Country Code</u>	DE	
<u>Entity Tax Identification Number</u>	82-2863566	
<u>Entity Address Address Line 1</u>	16305 36th Avenue North	
<u>Entity Address Address Line 2</u>	Suite 100	
<u>Entity Address City Or Town</u>	Minneapolis	
<u>Entity Address State Or Province</u>	MN	
<u>Entity Address Postal Zip Code</u>	55446	
<u>Security 12b Title</u>	Common Stock, \$0.001 par value per share	
<u>Trading Symbol</u>	CELC	
<u>Security Exchange Name</u>	NASDAQ	
<u>Entity Interactive Data Current</u>	Yes	
<u>City Area Code</u>	763	
<u>Local Phone Number</u>	392-0767	

**Condensed Balance Sheets -
USD (\$)**

	Jun. 30, 2021	Dec. 31, 2020
<u>Current Assets:</u>		
<u>Cash and cash equivalents</u>	\$ 41,638,623	\$ 11,637,911
<u>Deposits</u>	22,009	22,009
<u>Deferred transaction costs</u>	121,307	0
<u>Payroll tax receivable</u>	190,000	190,000
<u>Prepaid assets</u>	279,544	317,040
<u>Total current assets</u>	42,251,483	12,166,960
<u>Property and equipment, net</u>	415,080	558,876
<u>Operating lease right-of-use assets</u>	142,766	230,911
<u>Total Assets</u>	42,809,329	12,956,747
<u>Current Liabilities:</u>		
<u>Accounts payable</u>	647,172	217,377
<u>Finance lease liabilities</u>	5,830	5,810
<u>Operating lease liabilities</u>	153,684	187,518
<u>Accrued expenses</u>	729,672	774,612
<u>Total current liabilities</u>	1,536,358	1,185,317
<u>Finance lease liabilities non current</u>	5,379	8,299
<u>Operating lease liabilities non current</u>	0	60,861
<u>Note payable, non-current</u>	14,233,068	0
<u>Total Liabilities</u>	15,774,805	1,254,477
<u>Stockholders' Equity:</u>		
<u>Preferred stock, \$0.001 par value: 2,500,000 shares authorized; 0 shares issued and outstanding as of June 30, 2021 and December 31, 2020</u>	0	0
<u>Common stock, \$0.001 par value: 25,000,000 shares authorized; 12,654,898 and 10,299,822 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively</u>	12,655	10,300
<u>Additional paid-in capital</u>	70,167,970	38,013,551
<u>Accumulated deficit</u>	(43,146,101)	(26,321,581)
<u>Total Stockholders' Equity</u>	27,034,524	11,702,270
<u>Total Liabilities and Stockholders' Equity</u>	\$ 42,809,329	\$ 12,956,747

**Condensed Balance Sheets
(Parenthetical) - \$ / shares**

Jun. 30, 2021 Dec. 31, 2020

Condensed Balance Sheets

<u>Preferred stock, par or stated value per share</u>	\$ 0.001	\$ 0.001
<u>Preferred stock, shares authorized</u>	2,500,000	2,500,000
<u>Preferred stock, shares issued</u>	0	0
<u>Preferred stock, shares outstanding</u>	0	0
<u>Common stock, par or stated value per share</u>	\$ 0.001	\$ 0.001
<u>Common stock, shares authorized</u>	25,000,000	25,000,000
<u>Common stock, shares issued</u>	12,654,898	10,299,822
<u>Common stock, shares outstanding</u>	12,654,898	10,299,822

Condensed Statements of Operations (unaudited) - USD (\$)	3 Months Ended		6 Months Ended	
	Jun. 30, 2021	Jun. 30, 2020	Jun. 30, 2021	Jun. 30, 2020
<u>Operating expenses:</u>				
<u>Research and development</u>	\$ 13,070,108	\$ 1,766,227	\$ 15,306,451	\$ 3,613,641
<u>General and administrative</u>	573,360	447,714	1,128,787	911,113
<u>Total operating expenses</u>	13,643,468	2,213,941	16,435,238	4,524,754
<u>Loss from operations</u>	(13,643,468)	(2,213,941)	(16,435,238)	(4,524,754)
<u>Other income (expense)</u>				
<u>Interest expense</u>	(391,187)	(31)	(391,210)	(64)
<u>Interest income</u>	1,803	11,983	2,191	75,834
<u>Loss on sale of fixed assets</u>	0	0	(263)	0
<u>Other income (expense), net</u>	(389,384)	11,952	(389,282)	75,770
<u>Net loss before income taxes</u>	(14,032,852)	(2,201,989)	(16,824,520)	(4,448,984)
<u>Income tax benefits</u>	0	0	0	0
<u>Net loss</u>	\$ (14,032,852)	\$ (2,201,989)	\$ (16,824,520)	\$ (4,448,984)
<u>Net loss per share, basic and diluted</u>	\$ (1.11)	\$ (0.21)	\$ (1.42)	\$ (0.43)
<u>Weighted average common shares outstanding, basic and diluted</u>	12,610,917	10,260,234	11,845,758	10,257,111

Condensed Statements of Changes in Stockholders' Equity - USD (\$)	Total	Common Stock	Additional Paid-In Capital	Retained Earnings (Accumulated Deficit)
Balance, shares at Dec. 31, 2019		10,253,988		
Balance, amount at Dec. 31, 2019	\$ 19,297,571	\$ 10,254	\$ 36,134,723	\$ (16,847,406)
Stock-based compensation	464,649	0	464,649	0
Net loss	(2,246,995)	\$ 0	0	(2,246,995)
Balance, shares at Mar. 31, 2020		10,253,988		
Balance, amount at Mar. 31, 2020	17,515,225	\$ 10,254	36,599,372	(19,094,401)
Balance, shares at Dec. 31, 2019		10,253,988		
Balance, amount at Dec. 31, 2019	19,297,571	\$ 10,254	36,134,723	(16,847,406)
Net loss	(4,448,984)			
Balance, shares at Jun. 30, 2020		10,289,253		
Balance, amount at Jun. 30, 2020	15,862,358	\$ 10,289	37,148,459	(21,296,390)
Balance, shares at Mar. 31, 2020		10,253,988		
Balance, amount at Mar. 31, 2020	17,515,225	\$ 10,254	36,599,372	(19,094,401)
Net loss	(2,201,989)	\$ 0	0	(2,201,989)
Stock-based compensation, shares		15,686		
Stock-based compensation, amount	423,193	\$ 16	423,177	0
Employee stock purchases, shares		4,678		
Employee stock purchases, amount	23,897	\$ 4	23,893	0
Issuance of common stock in an at-the-market ("ATM") offering, shares		14,901		
Issuance of common stock in an at-the-market ("ATM") offering, amount	154,142	\$ 15	154,127	0
Issuance costs associated with ATM offering	(52,110)	\$ 0	(52,110)	0
Balance, shares at Jun. 30, 2020		10,289,253		
Balance, amount at Jun. 30, 2020	15,862,358	\$ 10,289	37,148,459	(21,296,390)
Balance, shares at Dec. 31, 2020		10,299,822		
Balance, amount at Dec. 31, 2020	11,702,270	\$ 10,300	38,013,551	(26,321,581)
Net loss	(2,791,668)	0	0	(2,791,668)
Stock-based compensation, amount	449,098	\$ 0	449,098	0
Issuance of common stock in an at-the-market ("ATM") offering, shares		3,082		
Issuance of common stock in an at-the-market ("ATM") offering, amount	38,962	\$ 3	38,959	0
Issuance costs associated with ATM offering	(3,868)	\$ 0	(3,868)	0
Exercise of common stock warrants, shares		1,185		
Exercise of common stock warrants, amount	11,257	\$ 1	11,256	0
Exercise of common stock options, net of shares withheld for exercise price, shares		12,707		
Exercise of common stock options, net of shares withheld for exercise price, amount	0	\$ 13	(13)	0

<u>Issuance of common stock upon closing of follow-on offering, net of underwriting discounts and offering costs, shares</u>		1,971,100		
<u>Issuance of common stock upon closing of follow-on offering, net of underwriting discounts and offering costs, amount</u>	25,768,493	\$ 1,971	25,766,522	0
<u>Balance, shares at Mar. 31, 2021</u>		12,287,896		
<u>Balance, amount at Mar. 31, 2021</u>	35,174,544	\$ 12,288	64,275,505	(29,113,249)
<u>Balance, shares at Dec. 31, 2020</u>		10,299,822		
<u>Balance, amount at Dec. 31, 2020</u>	11,702,270	\$ 10,300	38,013,551	(26,321,581)
<u>Net loss</u>	(16,824,520)			
<u>Balance, shares at Jun. 30, 2021</u>		12,654,898		
<u>Balance, amount at Jun. 30, 2021</u>	27,034,524	\$ 12,655	70,167,970	(43,146,101)
<u>Balance, shares at Mar. 31, 2021</u>		12,287,896		
<u>Balance, amount at Mar. 31, 2021</u>	35,174,544	\$ 12,288	64,275,505	(29,113,249)
<u>Net loss</u>	(14,032,852)	0	0	(14,032,852)
<u>Stock-based compensation, amount</u>	540,317	\$ 3	540,314	0
<u>Employee stock purchases, shares</u>		5,496		
<u>Employee stock purchases, amount</u>	25,817	\$ 6	25,811	0
<u>Exercise of common stock options, net of shares withheld for exercise price, shares</u>		9,136		
<u>Exercise of common stock options, net of shares withheld for exercise price, amount</u>	36,859	\$ 9	36,850	0
<u>Stock-based compensation, shares</u>		2,964		
<u>Warrant issued - note payable</u>	289,839		289,839	0
<u>Issuance of common stock, licensing agreement, shares</u>		349,406		
<u>Issuance of common stock, licensing agreement, amount</u>	5,000,000	\$ 349	4,999,651	0
<u>Balance, shares at Jun. 30, 2021</u>		12,654,898		
<u>Balance, amount at Jun. 30, 2021</u>	\$ 27,034,524	\$ 12,655	\$ 70,167,970	\$ (43,146,101)

**Condensed Statements of
Cash Flows (unaudited) -
USD (\$)**

**6 Months Ended
Jun. 30, Jun. 30,
2021 2020**

Cash flows from operating activities:

<u>Net loss</u>	\$	\$
	(16,824,520)	(4,448,984)

Adjustments to reconcile net loss to net cash used for operations:

<u>Depreciation</u>	176,597	191,134
<u>Stock-based compensation</u>	989,415	887,842
<u>Issuance of common stock, licensing agreement</u>	5,000,000	0
<u>Amortization of debt issuance costs and discount</u>	81,571	0
<u>PIK interest</u>	93,397	0
<u>Loss on sale of fixed assets</u>	263	0

Changes in operating assets and liabilities:

<u>Prepaid assets and deposits</u>	37,496	41,952
<u>Accounts payable</u>	438,018	(59,025)
<u>Accrued expenses</u>	(124,940)	26,189
<u>Non-cash operating lease, net</u>	(6,550)	(28,754)
<u>Net cash used for operating activities</u>	(10,139,253)	(3,389,646)

Cash flows from investing activities:

<u>Purchases of property and equipment</u>	(57,897)	(66,589)
<u>Proceeds from sale of property and equipment</u>	500	0
<u>Net cash used for investing activities</u>	(57,397)	(66,589)

Cash flows from financing activities:

<u>Proceeds from exercise of common stock warrants</u>	11,257	0
<u>Proceeds from exercise of employee stock options</u>	36,859	0
<u>Proceeds from employee stock purchases</u>	25,817	23,897
<u>Proceeds from follow-on offering, net of underwriting discounts and offering costs</u>	25,768,493	0
<u>Proceeds from note payable, net of debt issuance costs and discount of \$652,061</u>	14,347,939	0
<u>Gross proceeds from an ATM offering</u>	38,962	154,142
<u>Payments for secondary registration statement costs</u>	(29,065)	(23,367)
<u>Payments for finance leases</u>	(2,900)	(2,880)
<u>Net cash provided by financing activities</u>	40,197,362	151,792
<u>Net change in cash and cash equivalents</u>	30,000,712	(3,304,443)

Cash and cash equivalents:

<u>Beginning of period</u>	11,637,911	18,735,002
<u>End of period</u>	41,638,623	15,430,559

Supplemental disclosures of non-cash investing and financing activities:

<u>Offering and registration statement costs included in accounts payable and accrued expenses</u>	96,111	0
<u>Issuance of common stock warrants and final fee recognized as discount to note payable</u>	\$ 964,839	\$ 0

Organization

**6 Months Ended
Jun. 30, 2021**

Organization

Note 1. Organization

1. Organization

Nature of Business

Celcuity Inc., a Delaware corporation (the “Company”), is a clinical-stage biotechnology company seeking to extend the lives of cancer patients by pursuing an integrated companion diagnostic (CDx) and therapeutic (Rx) strategy. Our CELsignia companion diagnostic platform is uniquely able to analyze live patient tumor cells to identify new groups of cancer patients likely to benefit from targeted therapies. This enables a CELsignia CDx to support advancement of new indications for already approved targeted therapies. Our therapeutic efforts are focused on in-licensing and developing molecularly targeted therapies that address the same cancer driver our companion diagnostics can identify. By pursuing an integrated companion diagnostic and therapeutic strategy, we believe we are uniquely positioned to achieve our goal of helping cancer patients receive the therapeutic best suited to treat their cancer driver. The Company was co-founded in 2012 by Brian F. Sullivan and Dr. Lance G. Laing and is based in Minnesota. The Company has not generated any revenues to date.

Follow-on Offering

On July 1, 2021, the Company completed a follow-on offering whereby it sold 2,250,000 shares of common stock at a public offering price of \$25.00 per share. The aggregate gross proceeds from the sale of shares in the follow-on offering was approximately \$56.3 million before deducting underwriting discounts of approximately \$3.4 million and offering expenses of approximately \$0.1 million.

Summary of Significant Accounting Policies

6 Months Ended
Jun. 30, 2021

[Summary of Significant Accounting Policies](#)

[Note 2. Summary of Significant Accounting Policies](#)

2. Basis of Presentation, Summary of Significant Accounting Policies and Recent Accounting Pronouncements

Basis of Presentation

The accompanying unaudited financial statements include the accounts of the Company and have been prepared in accordance with Article 10 of Regulation S-X promulgated by the Securities and Exchange Commission (“SEC”). Accordingly, as permitted by Article 10, the unaudited financial statements do not include all of the information required by accounting principles generally accepted in the United States (“U.S. GAAP”). The balance sheet at December 31, 2020 was derived from the audited financial statements at that date and does not include all the disclosures required by U.S. GAAP. In the opinion of management, all adjustments which are of a normal recurring nature and necessary for a fair presentation have been reflected in the financial statements. These unaudited condensed financial statements should be read in conjunction with the audited financial statements as of and for the year ended December 31, 2020 and the related footnotes thereto included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2020. Operating results for the three and six months ended June 30, 2021 are not necessarily indicative of the results to be expected during the remainder of the current year or for any future period.

Accounting Estimates

Management uses estimates and assumptions in preparing these unaudited condensed financial statements in accordance with U.S. GAAP. Those estimates and assumptions affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities, and the reported revenues and expenses. Actual results could differ from those estimates and the difference could be material. Significant items subject to such estimates and assumptions include the valuation of stock-based compensation and prepaid or accrued clinical trial costs.

Risks and Uncertainties

The Company is subject to risks common to companies in the development stage including, but not limited to, dependency on the clinical and commercial success of its diagnostic tests, ability to obtain regulatory approval of its diagnostic tests, the clinical and commercial success of its initial drug product, gedatolisib, the need for substantial additional financing to achieve its goals, uncertainty of broad adoption of its approved products, if any, by physicians and consumers, and significant competition.

Clinical Trial Costs

The Company records prepaid assets or accrued expenses for prepaid or estimated clinical trial costs conducted by third-party service providers, which includes the conduct of preclinical studies and clinical trials. These costs can be a significant component of the Company’s research and development expenses. The Company accrues for these costs based on factors such as estimates of the work completed and in accordance with service agreements with its third-party service providers. The Company makes significant judgments and estimates in determining the accrued liabilities balance in each reporting period. As actual costs become known, the Company adjusts its prepaid assets or accrued expenses. The Company has not experienced any material differences between accrued costs and actual costs incurred. However, the status and timing of actual services performed, number of patients enrolled, and the rate of patient enrollments may vary from the Company’s estimates, resulting in an adjustment to expense in future periods.

Changes in these estimates that result in material changes to the Company's prepaid assets or accrued expenses could materially affect the Company's results of operations.

Application of New or Revised Accounting Standards

Pursuant to the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"), a company constituting an "emerging growth company" is, among other things, entitled to rely upon certain reduced reporting requirements. The Company is an emerging growth company but has irrevocably elected not to take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards. As a result, the Company will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for public companies that are not emerging growth companies.

Recently Adopted Accounting Pronouncements

In August 2020, the FASB issued ASU No. 2020-06, Debt - Debt with Conversion and other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity ("ASU 2020-06"), which simplifies accounting for convertible instruments by removing major separation models required under current U.S. GAAP. ASU 2020-06 removes certain settlement conditions that are required for equity contracts to qualify for derivative scope exceptions and also simplifies the diluted earnings per share calculation in certain areas. The standard is effective for public business entities, excluding entities eligible to be smaller reporting companies as defined by the SEC, for fiscal years and interim periods within those fiscal years beginning after December 15, 2021. For all other entities, the standard will be effective for fiscal years beginning after December 15, 2023. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, and adoption must be as of the beginning of the Company's annual fiscal year. The Company's early adoption of this accounting standard on April 8, 2021, in conjunction with the closing of a loan agreement, did not have an impact on the Company's financial statements and related disclosures.

Net Loss Per Common Share

**6 Months Ended
Jun. 30, 2021**

Net Loss Per Common Share

Note 3. Net Loss Per Common Share

Basic and diluted net loss per common share is determined by dividing net loss attributable to common stockholders by the weighted-average common shares outstanding during the period. For all periods presented, the common shares underlying the options and warrants have been excluded from the calculation because their effect would be anti-dilutive. Therefore, the weighted-average shares outstanding used to calculate both basic and diluted loss per common share are the same.

For the three and six months ended June 30, 2021 and 2020, potentially dilutive securities excluded from the computations of diluted weighted-average shares outstanding were options to purchase 1,023,513 and 723,194 shares of common stock, respectively, warrants to purchase 378,442 and 353,585 shares of common stock, respectively, and 2,964 and 15,686 shares of restricted common stock, respectively.

Commitments

6 Months Ended
Jun. 30, 2021

Commitments

Note 4. Commitments

4. Commitments

Operating and Finance Leases

The Company leases its corporate space in Minneapolis, Minnesota. In September 2017, the Company entered into a non-cancelable operating lease agreement for building space. The new lease commenced, and the Company moved to the facility in May 2018, in conjunction with the termination of its then existing lease. Rent expense is recorded on a straight-line basis over the lease term. In July 2020 the Company signed an amendment to extend this lease through April 30, 2022. The lease amendment provides for monthly rent, real estate taxes and operating expenses. As a result of the lease amendment, the Company recorded an incremental \$197,211 in the operating right-of-use ("ROU") asset and lease liability.

The lease agreement, as amended, includes the option to extend the term for one additional year. The option to extend is at the Company's discretion and because the Company has not determined if the option to extend will be exercised, the extended lease term is not included in the ROU assets and lease liabilities. The Company regularly evaluates the renewal options and when it is reasonably certain of exercise, the Company will include the renewal period in its lease term.

In May 2018, the Company entered into a non-cancelable finance lease agreement for office equipment with a five-year term. The underlying assets are included in furniture and equipment. The lease contains a bargain purchase option at the end of the lease.

When an implicit rate is not provided, the Company uses its incremental borrowing rate based on the information available at the lease commencement date in determining the present value of the lease payments.

Supplemental balance sheet information consisted of the following at June 30, 2021:

Operating Lease	
Right-of-use assets	\$ 142,766
Operating lease liability	
Less: short term portion	(153,684)
Long term portion	\$ -
Finance Lease	
Furniture and equipment	\$ 28,932
Less: Accumulated depreciation	(17,841)
Net book value of property and equipment under finance lease	\$ 11,091
Finance lease liability	
Less: short term portion	(5,830)
Long term portion	\$ 5,379

Maturity analysis under lease agreements consisted of the following as of June 30, 2021:

	Operating Leases	Finance Leases
2021	\$ 97,411	\$ 3,627
2022	64,940	7,255
2023	-	3,023
Total minimum lease payments	162,351	13,905
Less: Present value discount	(8,667)	(78)
Less amount representing services	-	(2,618)

Present value of net minimum lease payments	\$ 153,684	\$ 11,209
Weighted Average	Remaining Lease Term	Discount Rate
Operating lease	0.8 years	4.0%
Finance lease	1.9 years	1.0%

Lease costs for the period ended June 30, 2021:

	Three- month Period	Six- month Period
Operating lease cost	\$ 43,727	\$ 89,157
Finance lease cost:		
Amortization	1,447	2,893
Interest	21	45
Variable lease cost	19,869	39,738
	<u>\$ 65,064</u>	<u>\$ 131,833</u>

Supplemental cash flow information related to leases for the period ended June 30, 2021:

	Three- month Period	Six- month Period
Cash paid for amounts included in operating and finance leases:		
Operating cash outflow from operating leases	\$ 66,872	\$ 135,446
Operating cash outflow from finance leases	21	45
Financing cash outflow from finance leases	1,451	2,900
	<u>\$ 68,344</u>	<u>\$ 138,391</u>

Clinical Research Studies

The Company enters into contracts in the normal course of business for clinical trials, preclinical studies, manufacturing and other services and products for operating purposes. The Company currently has five Phase II clinical trial agreements in place to evaluate targeted therapies selected with one of our CELsignia tests. The Company also has a license agreement in place with Pfizer to research, develop, manufacture and commercialize gedatolisib. Timing of milestone payments are uncertain and the contracts generally provide for termination following a certain period after notice, therefore the Company believes that non-cancelable obligations under the agreements are not material.

Stockholders' Equity

**6 Months Ended
Jun. 30, 2021**

Stockholders' Equity

Note 5. Stockholders' Equity

5. Stockholders' Equity

On February 26, 2021, the Company completed a follow-on offering whereby it sold 1,971,100 shares of common stock (including 257,100 shares of common stock in connection with the full exercise of the underwriters' option to purchase additional shares) at a public offering price of \$14.00 per share. The aggregate gross proceeds from the sale of shares in the follow-on offering, including the sale of shares pursuant to the full exercise of the underwriters' option to purchase additional shares, was approximately \$27.6 million before deducting underwriting discounts of approximately \$1.6 million and offering expenses of approximately \$0.2 million.

On June 5, 2020, the Company entered into an At Market Issuance Sales Agreement (the "ATM Agreement") with B. Riley FBR, Inc. (the "Agent"). Pursuant to the ATM Agreement, the Company was able to offer and sell from time to time, at its option, shares of common stock having an aggregate offering price of up to \$10,000,000, par value \$0.001 per share (the "Placement Shares"), through the Agent.

The Placement Shares were registered under the Securities Act of 1933, as amended, pursuant to the Registration Statement on Form S-3 (File No. 333-227466), which was originally filed with the SEC on September 21, 2018 and declared effective by the SEC on October 4, 2018, the base prospectus contained within the Registration Statement, and a prospectus supplement that was filed on June 5, 2020. Sales of the Company's common stock, if any, under this prospectus supplement were able to be made by any method deemed to be an "at the market offering" as defined in Rule 415 promulgated under the Securities Act of 1933, as amended.

During the six months ended June 30, 2021, the Company sold 3,082 shares of common stock pursuant to the ATM Agreement, at an average selling price of \$12.64 per share.

On February 23, 2021, in conjunction with the Company's follow-on offering, the ATM Agreement was terminated.

Stock-Based Compensation

6 Months Ended
Jun. 30, 2021

Stock-Based Compensation

Note 6. Stock-Based Compensation

6. Stock-Based Compensation

The following table summarizes the activity for all stock options outstanding for the six months ended June 30:

	2021		2020	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Options outstanding at beginning of year	849,949	\$ 9.33	585,215	\$ 14.37
Granted	218,050	24.70	151,231	7.14
Exercised	(39,620)	7.32	-	-
Forfeited	(4,866)	7.67	(13,252)	11.54
Balance at June 30	1,023,513	\$ 12.69	723,194	\$ 9.71
Options exercisable at June 30:	504,189	\$ 9.64	305,778	\$ 9.68

Weighted Average Grant Date Fair Value for options granted during the period:

	\$ 16.39	\$ 4.55
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The following table summarizes additional information about stock options outstanding and exercisable at June 30, 2021:

Options Outstanding	Options Outstanding			Options Exercisable			
	Options Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Aggregate Intrinsic Value	Options Exercisable	Weighted Average Exercise Price	Aggregate Intrinsic Value
	1,023,513	7.99	\$ 12.69	\$12,101,685	504,189	\$ 9.64	\$7,271,109

The Company recognized stock-based compensation expense for stock options of \$520,361 and \$414,272 for the three months ended June 30, 2021 and 2020, respectively and \$938,553 and \$864,937 for the six months ended June 30, 2021 and 2020, respectively. In May 2020, the Company modified the exercise price on 203,750 stock option awards to \$5.10, the closing market price on the Nasdaq Capital Market on May 14, 2020. No director or officer awards were modified. The effect on stock-based compensation was \$12,790 and \$51,000 for the three months ended June 30, 2021 and 2020, respectively and \$26,239 and \$51,000 for the six months ended June 30, 2021 and 2020. The effect on stock-based compensation over the remaining service period will be approximately \$109,000.

The Black-Scholes option-pricing model was used to estimate the fair value of equity-based awards with the following weighted-average assumptions for the six months ended June 30:

	2021	2020
Risk-free interest rate	0.63% - 1.14%	0.35% - 1.66%
Expected volatility	76.6% - 76.9%	73.3% - 74.4%
Expected life (years)	5.0 to 6.08	5.5 to 6.12
Expected dividend yield	0%	0%

The inputs for the Black-Scholes valuation model require management's significant assumptions. Prior to the Company's initial public offering, the price per share of common stock was determined by the Company's board based on recent prices of common stock sold in private

offerings. Subsequent to the initial public offering, the price per share of common stock is determined by using the closing market price on the Nasdaq Capital Market on the grant date. The risk-free interest rates are based on the rate for U.S. Treasury securities at the date of grant with maturity dates approximately equal to the expected life at the grant date. The expected life is based on the simplified method in accordance with the SEC Staff Accounting Bulletin Nos. 107 and 110. The expected volatility is estimated based on historical volatility information of peer companies that are publicly available in combination with the Company's calculated volatility since being publicly traded.

All assumptions used to calculate the grant date fair value of non-employee options are generally consistent with the assumptions used for options granted to employees. In the event the Company terminates any of its consulting agreements, the unvested options issued in connection with the agreements would also be cancelled.

Restricted stock awards were granted to two members of the Company's board during the three months ended June 30, 2021 and 2020. The Company had 2,964 and 15,686 shares of restricted stock outstanding as of June 30, 2021 and 2020, respectively, and 15,686 and 0 shares of restricted stock vested during the three months ended June 30, 2021 and 2020. The Company recognized stock-based compensation expense for restricted stock of \$18,112 and \$10,912 for the three months ended June 30, 2021 and 2020, respectively and \$38,567 and \$10,912 for the six months ended June 30, 2021 and 2020.

The Company initially reserved a maximum of 750,000 shares of common stock for issuance under the 2017 Amended and Restated Stock Incentive Plan (the "2017 Plan"). The number of shares reserved for issuance was automatically increased by 102,540 shares on January 1, 2020 and by 102,998 shares on January 1, 2021 and will increase automatically on January 1 of each of 2022 through 2027 by the number of shares equal to 1.0% of the aggregate number of outstanding shares of Company common stock as of the immediately preceding December 31. At the Annual Meeting held on May 12, 2021, the stockholders approved a one-time, 500,000 increase to the number of shares reserved for issuance under the 2017 Plan. However, the Company's board may reduce the amount of the increase in any particular year. The total remaining shares available for grant under the Company's 2017 Plan as of June 30, 2021 was 585,772.

Total unrecognized compensation cost related to stock options and restricted stock is estimated to be recognized as follows:

2021	\$1,247,486
2022	2,034,829
2023	1,476,348
2024	979,053
2025	246,916
Total estimated compensation cost to be recognized	<u>\$5,984,632</u>

The Company recognized stock-based compensation expense related to its employee stock purchase plan of \$1,844 and (\$1,991) for the three months ended June 30, 2021 and 2020, respectively and \$12,295 and \$11,993 for the six months ended June 30, 2021 and 2020, respectively. The Company initially reserved a total of 100,000 shares for issuance under the employee stock purchase plan. The number of shares reserved for issuance was automatically increased by 51,270 shares on January 1, 2020 and 51,499 shares on January 1, 2021 and will increase automatically on each subsequent January 1 by the number of shares equal to 0.5% of the total outstanding number of shares of Company common stock as of the immediately preceding December 31. However, the Company's board may reduce the amount of the increase in any particular year. The total remaining shares available for issuance under the employee stock purchase plan as of June 30, 2021 was 158,214.

The Company recognized total stock-based compensation expense as follows for the three and six months ended June 30:

	Three Months		Six Months Ended	
	2021	2020	2021	2020
Stock-based compensation expense in operating expenses:				
Research and development	\$ 328,077	\$ 265,446	\$ 583,258	\$ 558,562
General and administrative	212,240	157,747	406,157	329,280
Total	\$ 540,317	\$ 423,193	\$ 989,415	\$ 887,842

[Debt](#)[Note 7 . Debt](#)**7. Debt**

On April 8, 2021, the Company entered into a loan and security agreement (the “Loan Agreement”) with Innovatus Life Sciences Lending Fund I, LP, a Delaware limited partnership (“Innovatus”) in its capacity as Collateral Agent and sole Lender. The Lender agreed to loan up to \$25 million in three tranches consisting of (i) a \$15.0 million non-contingent term A loan that was funded on April 8, 2021, (ii) a \$5 million term B loan to be funded upon request of the Company no later than March 31, 2022, and (iii) a \$5 million term C loan to be funded upon request of the Company no later than March 31, 2023 (collectively the “Term Loans”). Funding of the term B and C loan is subject to the Company’s ability to achieve certain milestones. The Innovatus Loan Agreement is secured by a lien covering substantially all assets of the Company.

The loan agreement also contains certain events of default, warranties and covenants of the Company. In connection with each funding of the Term Loans, the Company is required to issue Innovatus a warrant (the “Warrants”) to purchase a number of shares of the Company’s stock equal to 2.5% of the principal amount of the relevant Term Loan funded divided by the exercise price, which will be based on the lower of (i) \$14.40 per share or (ii) the volume weighted price per share of the Company’s stock for the five-trading day period ending on the last trading day immediately preceding the funding date of the Term B or Term C Loan, as applicable. The warrants may be exercised on a cashless basis and are immediately exercisable through the tenth anniversary of the applicable funding date. In connection with the first tranche of the Term Loans, the Company issued a warrant to Innovatus to purchase 26,042 shares of the Company’s common stock at an exercise price of \$14.40 per share. The Company evaluated the warrant under ASC470, debt, and recognized an additional debt discount of approximately \$0.3 million based on the relative fair value of the base instruments and warrants. The Company calculated the fair value of the warrant using the Black-Scholes model. The Company is also required to maintain a minimum cash balance in agreement with the term loans’ default terms.

The Company is entitled to make interest-only payments for thirty-six months, or up to forty-eight months if certain conditions are met. The Term Loans will mature on the fifth anniversary of the initial funding date and will bear interest at a rate equal to sum of (a) the greater of (i) Prime Rate (as defined in the loan agreement) or (ii) 3.25%, plus (b) 5.70%. The effective interest rate is 11.36%. Additionally, the Company elected to make 2.7% of the interest rate as payable in kind, which shall accrue as principal monthly. The Company is obligated to pay the Lender (i) a non-refundable facility fee in the amount of 1.00% of each term loan that is funded (the “Facility Fee”), and (ii) a final fee equal to 4.50% of the aggregate amount of the term loans funded (the “Final Fee”). In connection with the funding of the first tranche of the Term Loans, a final fee of approximately \$0.7 million was recorded as additional principal and as a debt discount, and a facility fee of approximately \$0.1 million was recorded as additional debt discount. The Company has the option to prepay the loan at any time following the first anniversary of the loan closing, with tiered prepayment fees ranging from 0 – 2% based on when the prepayment would occur.

Innovatus also has the right, at its election, after June 1, 2021 and until the third anniversary of the Loan Agreement, to convert up to 20% of the outstanding principal amount of all Terms Loans made under the Loan Agreement into shares of the Company’s common stock at a price per share equal to the volume weighted average closing price of the Company’s stock for the 5-trading day period ending on the last trading day immediately preceding the execution of the Loan Agreement (the “Conversion Right”).

In connection with the loan agreement and the funding of the first tranche of the Term Loans, the Company incurred debt issuance costs of approximately \$0.5 million. The debt issuance costs, and the debt discount are amortized to interest expense using the effective interest method over the life of the Term Loans. The carrying value of the debt approximates fair value as of June 30, 2021.

Long-term debt consisted of the following:

	June 30, 2021
Note payable	\$15,000,000
Add: PIK interest (added to principal)	93,397
Add: final fee	675,000
Less: unamortized debt issuance costs	(466,482)
Less: unamortized debt discount	(1,068,847)
Total long-term debt	<u>\$14,233,068</u>

Future principal payments, including the final fee, are as follows:

	Years Ending December 31,
2024	\$ 5,660,024
2025	7,546,698
2026	2,561,675
Total	<u>\$15,768,397</u>

License Agreement

**6 Months Ended
Jun. 30, 2021**

[License Agreement](#)

[Note 8. License Agreement](#)

8. License Agreement

On April 8th, the Company entered into a license agreement with Pfizer to research, develop, manufacture and commercialize gedatolisib, a potent, well-tolerated, reversible dual inhibitor that targets PI3K and mTOR, for the treatment, diagnosis and prevention of all diseases. The Company paid Pfizer \$5.0 million in upfront fees and issued to Pfizer \$5.0 million of shares of the Company's common stock pursuant to an Equity Grant Agreement. The upfront payment and the issuance of shares were expensed to research & development in full for the three months ending June 30, 2021.

The Company is also required to make milestone payments to Pfizer upon achievement of certain development and commercial milestone events, up to an aggregate of \$335.0 million. Additionally, the Company will pay Pfizer tiered royalties on sales of gedatolisib at percentages ranging from the low to mid-teens, which may be subject to deductions for expiration of valid claims, amounts due under third-party licenses and generic competition. Unless earlier terminated, the License Agreement will expire upon the expiration of all royalty obligations. The royalty period will expire on a country-by-country basis upon the later of (a) 12 years following the date of first commercial sale of such product in such country, (b) the expiration of all regulatory or data exclusivity in such country for such product or (c) the date upon which the manufacture, use, sale, offer for sale or importation of such product in such country would no longer infringe, but for the license granted in the License Agreement, a valid claim of a licensed patent right.

The Company has the right to terminate the License Agreement for convenience upon 90 days' prior written notice. Pfizer may not terminate the agreement for convenience. Either the Company or Pfizer may terminate the License Agreement if the other party is in material breach and such breach is not cured within the specified cure period. In addition, either the Company or Pfizer may terminate the License Agreement in the event of specified insolvency events involving the other party.

Subsequent Events

**6 Months Ended
Jun. 30, 2021**

Subsequent Events

Note 9. Subsequent events

9. Subsequent Events

As noted in footnote 2, on July 1, 2021, the Company completed a follow-on offering whereby it sold 2,250,000 shares of common stock at a public offering price of \$25.00 per share.

On July 19, 2021, the Company signed an amendment to exercise the option to extend the lease for a period of one year. The commencement of the extended period is May 1, 2022 and will terminate on April 30, 2023.

Summary of Significant Accounting Policies (Policies)

6 Months Ended
Jun. 30, 2021

[Summary of Significant Accounting Policies](#)

[Basis of Presentation](#)

The accompanying unaudited financial statements include the accounts of the Company and have been prepared in accordance with Article 10 of Regulation S-X promulgated by the Securities and Exchange Commission ("SEC"). Accordingly, as permitted by Article 10, the unaudited financial statements do not include all of the information required by accounting principles generally accepted in the United States ("U.S. GAAP"). The balance sheet at December 31, 2020 was derived from the audited financial statements at that date and does not include all the disclosures required by U.S. GAAP. In the opinion of management, all adjustments which are of a normal recurring nature and necessary for a fair presentation have been reflected in the financial statements. These unaudited condensed financial statements should be read in conjunction with the audited financial statements as of and for the year ended December 31, 2020 and the related footnotes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2020. Operating results for the three and six months ended June 30, 2021 are not necessarily indicative of the results to be expected during the remainder of the current year or for any future period.

[Accounting Estimates](#)

Management uses estimates and assumptions in preparing these unaudited condensed financial statements in accordance with U.S. GAAP. Those estimates and assumptions affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities, and the reported revenues and expenses. Actual results could differ from those estimates and the difference could be material. Significant items subject to such estimates and assumptions include the valuation of stock-based compensation and prepaid or accrued clinical trial costs.

[Risks and Uncertainties](#)

The Company is subject to risks common to companies in the development stage including, but not limited to, dependency on the clinical and commercial success of its diagnostic tests, ability to obtain regulatory approval of its diagnostic tests, the clinical and commercial success of its initial drug product, gedatolisib, the need for substantial additional financing to achieve its goals, uncertainty of broad adoption of its approved products, if any, by physicians and consumers, and significant competition.

[Clinical Trial Costs](#)

The Company records prepaid assets or accrued expenses for prepaid or estimated clinical trial costs conducted by third-party service providers, which includes the conduct of preclinical studies and clinical trials. These costs can be a significant component of the Company's research and development expenses. The Company accrues for these costs based on factors such as estimates of the work completed and in accordance with service agreements with its third-party service providers. The Company makes significant judgments and estimates in determining the accrued liabilities balance in each reporting period. As actual costs become known, the Company adjusts its prepaid assets or accrued expenses. The Company has not experienced any material differences between accrued costs and actual costs incurred. However, the status and timing of actual services performed, number of patients enrolled, and the rate of patient enrollments may vary from the Company's estimates, resulting in an adjustment to expense in future periods. Changes in these estimates that result in material changes to the Company's prepaid assets or accrued expenses could materially affect the Company's results of operations.

[Application of New or Revised Accounting Standards](#)

Pursuant to the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"), a company constituting an "emerging growth company" is, among other things, entitled to rely upon certain reduced reporting requirements. The Company is an emerging growth company but has irrevocably elected not to take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards. As a result, the Company will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for public companies that are not emerging growth companies.

[Recently Adopted Accounting Pronouncements](#)

In August 2020, the FASB issued ASU No. 2020-06, Debt - Debt with Conversion and other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity ("ASU 2020-06"), which simplifies accounting for convertible instruments by removing major separation models required under current U.S. GAAP. ASU 2020-06 removes certain settlement conditions that are required for equity contracts to qualify for derivative scope

exceptions and also simplifies the diluted earnings per share calculation in certain areas. The standard is effective for public business entities, excluding entities eligible to be smaller reporting companies as defined by the SEC, for fiscal years and interim periods within those fiscal years beginning after December 15, 2021. For all other entities, the standard will be effective for fiscal years beginning after December 15, 2023. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, and adoption must be as of the beginning of the Company's annual fiscal year. The Company's early adoption of this accounting standard on April 8, 2021, in conjunction with the closing of a loan agreement, did not have an impact on the Company's financial statements and related disclosures.

Commitments (Tables)

**6 Months Ended
Jun. 30, 2021**

Commitments

Schedule of supplemental balance sheet information related to leases

Operating Lease	
Right-of-use assets	\$ 142,766
Operating lease liability	\$ 153,684
Less: short term portion	(153,684)
Long term portion	<u>\$ -</u>
Finance Lease	
Furniture and equipment	\$ 28,932
Less: Accumulated depreciation	(17,841)
Net book value of property and equipment under finance lease	<u>\$ 11,091</u>
Finance lease liability	\$ 11,209
Less: short term portion	(5,830)
Long term portion	<u>\$ 5,379</u>

Schedule of maturity analysis under lease agreements

Maturity analysis under lease agreements consisted of the following as of June 30, 2021:

	Operating Leases	Finance Leases
2021	\$ 97,411	\$ 3,627
2022	64,940	7,255
2023	-	3,023
Total minimum lease payments	<u>162,351</u>	<u>13,905</u>
Less: Present value discount	(8,667)	(78)
Less amount representing services	-	(2,618)
Present value of net minimum lease payments	<u>\$ 153,684</u>	<u>\$ 11,209</u>

	Remaining Lease Term	Discount Rate
Operating lease	0.8 years	4.0%
Finance lease	1.9 years	1.0%

Lease costs for the period ended June 30, 2021:

	Three- month Period	Six- month Period
Operating lease cost	\$ 43,727	\$ 89,157
Finance lease cost:		
Amortization	1,447	2,893
Interest	21	45
Variable lease cost	19,869	39,738
	<u>\$ 65,064</u>	<u>\$ 131,833</u>

Supplemental cash flow information related to leases for the period ended June 30, 2021:

Three- month Period	Six- month Period
------------------------------------	----------------------------------

Cash paid for amounts included in operating and finance leases:

Operating cash outflow from operating leases	\$ 66,872	\$ 135,446
Operating cash outflow from finance leases	21	45
Financing cash outflow from finance leases	1,451	2,900
	<u>\$ 68,344</u>	<u>\$ 138,391</u>

**Stock-Based Compensation
(Tables)**

**6 Months Ended
Jun. 30, 2021**

[Stock-Based Compensation](#)

[Schedule of activity for all
stock options outstanding](#)

	2021		2020	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Options outstanding at beginning of year	849,949	\$ 9.33	585,215	\$ 14.37
Granted	218,050	24.70	151,231	7.14
Exercised	(39,620)	7.32	-	-
Forfeited	(4,866)	7.67	(13,252)	11.54
Balance at June 30	<u>1,023,513</u>	<u>\$ 12.69</u>	<u>723,194</u>	<u>\$ 9.71</u>
Options exercisable at June 30:	<u>504,189</u>	<u>\$ 9.64</u>	<u>305,778</u>	<u>\$ 9.68</u>

Weighted Average Grant Date Fair Value for options granted during the period:	\$ 16.39	\$ 4.55
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[Schedule of stock options
outstanding](#)

Options Outstanding	Options Outstanding			Options Exercisable		
	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Aggregate Intrinsic Value	Options Exercisable	Weighted Average Exercise Price	Aggregate Intrinsic Value
1,023,513	7.99	\$ 12.69	\$12,101,685	504,189	\$ 9.64	\$7,271,109

[Schedule of fair value of
equity-based awards](#)

	2021	2020
Risk-free interest rate	0.63% - 1.14%	0.35% - 1.66%
Expected volatility	76.6% - 76.9%	73.3% - 74.4%
Expected life (years)	5.0 to 6.08	5.5 to 6.12
Expected dividend yield	0%	0%

[Schedule of unrecognized
compensation cost](#)

2021	\$1,247,486
2022	2,034,829
2023	1,476,348
2024	979,053
2025	246,916
Total estimated compensation cost to be recognized	<u>\$5,984,632</u>

[Schedule of stock-based
compensation expense](#)

	Three Months Ended		Six Months Ended	
	2021	2020	2021	2020
Stock-based compensation expense in operating expenses:				
Research and development	\$ 328,077	\$ 265,446	\$ 583,258	\$ 558,562
General and administrative	212,240	157,747	406,157	329,280
Total	<u>\$ 540,317</u>	<u>\$ 423,193</u>	<u>\$ 989,415</u>	<u>\$ 887,842</u>

Debt (Tables)**6 Months Ended
Jun. 30, 2021****Stock-Based Compensation****Schedule of Long-term debt**

	June 30, 2021
Note payable	\$15,000,000
Add: PIK interest (added to principal)	93,397
Add: final fee	675,000
Less: unamortized debt issuance costs	(466,482)
Less: unamortized debt discount	(1,068,847)
Total long-term debt	<u>\$14,233,068</u>

Schedule of Future principal payments

	Years Ending December 31,
2024	\$ 5,660,024
2025	7,546,698
2026	2,561,675
Total	<u>\$15,768,397</u>

**Organization (Details
Narrative) - USD (\$)
\$ / shares in Units, \$ in
Millions**

**1 Months Ended 6 Months Ended
Feb. 26, 2021 Jun. 30, 2021**

<u>Issuance of common stock upon closing of follow-on offering, net shares</u>	1,971,100	
<u>Deducting underwriting discounts</u>	\$ 1.6	
<u>Offering expenses</u>	\$ 0.2	
<u>July 1, 2021 [Member]</u>		
<u>Offering Price Per Share</u>		\$ 25.00
<u>Issuance of common stock upon closing of follow-on offering, net shares</u>		2,250,000
<u>Proceeds from follow on offering</u>		\$ 56.3
<u>Deducting underwriting discounts</u>		3.4
<u>Offering expenses</u>		\$ 0.1

**Net Loss Per Common Share
(Details Narrative) - shares**

**6 Months Ended
Jun. 30, 2021 Jun. 30, 2020**

Restricted Stock [Member]

Antidilutive securities excluded from computation of earnings per share 2,964 15,686

Stock Option [Member]

Antidilutive securities excluded from computation of earnings per share 1,023,513 723,194

Warrant [Member]

Antidilutive securities excluded from computation of earnings per share 378,442 353,585

**Commitments (Details) -
USD (\$)**

Jun. 30, 2021 Dec. 31, 2020

Commitments

<u>Right-of-use asset</u>	\$ 142,766	\$ 230,911
<u>Operating lease liability</u>	153,684	
<u>Less: short term portion</u>	(153,684)	\$ (187,518)
<u>Long term portion</u>	0	
<u>Furniture and equipment</u>	28,932	
<u>Less: Accumulated depreciation</u>	(17,841)	
<u>Net book value of property and equipment under finance lease</u>	11,091	
<u>Finance lease liability</u>	11,209	
<u>Less: short term portions</u>	(5,830)	
<u>Long terms portions</u>	\$ 5,379	

Commitments (Details 1)	Jun. 30, 2021 USD (\$)
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Commitments

<u>2021</u>	\$ 97,411
<u>2022</u>	64,940
<u>2023</u>	0
<u>Total minimum lease payments</u>	162,351
<u>Less: present value discount</u>	(8,667)
<u>Less amount representing services</u>	0
<u>Present value of net minimum lease payments</u>	153,684
<u>2021</u>	3,627
<u>2022</u>	7,255
<u>2023</u>	3,023
<u>Total minimum lease payments</u>	13,905
<u>Less: present value discounts</u>	(78)
<u>Less amount representing services</u>	(2,618)
<u>Present value of net minimum lease payments</u>	\$ 11,209

Commitments (Details 2)

**6 Months Ended
Jun. 30, 2021**

Commitments

Operating lease, weighted average remaining lease term 9 months 18 days

Operating lease, weighted average discount rate, percent 4.00%

Finance lease, weighted average remaining lease term 1 year 10 months 24 days

Finance lease, weighted average discount rate, percent 1.00%

Commitments (Details 3) - USD (\$)	3 Months Ended Jun. 30, 2021	6 Months Ended Jun. 30, 2021
<u>Commitments</u>		
<u>Operating lease cost</u>	\$ 43,727	\$ 89,157
<u>Finance lease cost:</u>		
<u>Amortization</u>	1,447	2,893
<u>Interest</u>	21	45
<u>Variable lease cost</u>	19,869	39,738
<u>Total lease cost</u>	\$ 65,064	\$ 131,833

**Commitments (Details 4) -
USD (\$)**

**3 Months Ended 6 Months Ended
Jun. 30, 2021 Jun. 30, 2021**

<u>Cash paid for amounts included in operating and finance leases:</u>		
<u>Operating cash outflow from operating leases</u>	\$ 66,872	\$ 135,446
<u>Operating cash outflow from finance leases</u>	21	45
<u>Financing cash outflow from finance leases</u>	1,451	2,900
<u>Total cash paid for amounts included in operating and finance leases</u>	\$ 68,344	\$ 138,391

**Commitments (Details
Narrative)**

**6 Months Ended
Jun. 30, 2021
USD (\$)**

Commitments

Increase in operating ROU asset and lease liability \$ 197,211

Stockholders Equity (Details Narrative) - USD (\$)	1 Months	6 Months			
	Ended	Ended	Feb. 26,	Mar. 31,	Jun. 05,
	2021	2021	2021	2020	2020
Public offering price	\$ 14.00				
Net proceeds	\$	27,600,000			
Net of underwriting commissions		1,600,000			
Offering expenses	\$ 200,000				
Issuance of common stock upon closing of follow-on offering, including shares of common stock	257,100				
Issuance of common stock upon closing of follow-on offering, net shares	1,971,100				
Common stock par value		\$ 0.001		\$ 0.001	
Placement Shares [Member] ATM Agreement [Member]					
Aggregate offering price, common stock shares					\$
					10,000,000
Common stock par value					\$ 0.001
Sale of stock number of shares issued in transaction		3,082			
Average selling price per share				\$ 12.64	

**StockBased Compensation
(Details) - Employee Stock
Option - \$ / shares**

**6 Months Ended
Jun. 30, 2021 Jun. 30, 2020**

<u>Shares options outstanding, beginning</u>	849,949	585,215
<u>Shares, granted</u>	218,050	151,231
<u>Shares, exercised</u>	(39,620)	
<u>shares, forfeited</u>	(4,866)	(13,252)
<u>Shares options outstanding, ending</u>	1,023,513	723,194
<u>Shares, options exercisable</u>	504,189	305,778
<u>Weighted average exercise price, beginning</u>	\$ 9.33	\$ 14.37
<u>Weighted average exercise price, granted</u>	24.70	7.14
<u>Weighted average exercise price, exercised</u>	7.32	
<u>Weighted average exercise price, forfeited</u>	7.67	11.54
<u>Weighted average exercise price, ending</u>	12.69	9.71
<u>Weighted average exercise price, options exercisable</u>	9.64	9.68
<u>Weighted average grant date fair value for options granted during the period:</u>	\$ 16.39	\$ 4.55

StockBased Compensation
(Details 1) - Employee Stock
Option

6 Months Ended
Jun. 30, 2021
USD (\$)
\$ / shares
shares

Options Outstanding shares	1,023,513
Options outstanding, weighted average remaining contractual life	7 years 11 months 26 days
Options outstanding, weighted average exercise price \$ / shares	\$ 12.69
Options outstanding, aggregate intrinsic value \$	\$ 12,101,685
Options exercisable shares	504,189
Options exercisable, weighted average exercise price \$ / shares	\$ 9.64
Options exercisable, aggregate intrinsic value \$	\$ 7,271,109

StockBased Compensation (Details 2) - Employee Stock Option	6 Months Ended	
	Jun. 30, 2021	Jun. 30, 2020
Expected dividend yield	0.00%	0.00%
Minimum Member		
Risk-free interest rate	0.63%	0.35%
Expected volatility	76.60%	73.30%
Expected life (years)	5 years	5 years 6 months
Maximum Member		
Risk-free interest rate	1.14%	1.66%
Expected volatility	76.90%	74.40%
Expected life (years)	6 years 29 days	6 years 1 month 13 days

**StockBased Compensation
(Details 3)**

**Jun. 30, 2021
USD (\$)**

Stock-Based Compensation

<u>2021</u>	\$ 1,247,486
<u>2022</u>	2,034,829
<u>2023</u>	1,476,348
<u>2024</u>	979,053
<u>2025</u>	246,916
<u>Total estimated compensation cost to be recognized</u>	\$ 5,984,632

StockBased Compensation (Details 4) - USD (\$)	3 Months Ended		6 Months Ended	
	Jun. 30, 2021	Jun. 30, 2020	Jun. 30, 2021	Jun. 30, 2020
<u>Stock-based compensation</u>	\$ 540,317	\$ 423,193	\$ 989,415	\$ 887,842
<u>Research And Development Expense</u>				
<u>Stock-based compensation</u>	328,077	265,446	583,258	558,562
<u>General And Administrative Expense</u>				
<u>Stock-based compensation</u>	\$ 212,240	\$ 157,747	\$ 406,157	\$ 329,280

StockBased Compensation (Details Narrative) - USD (\$)	3 Months Ended		6 Months Ended		May 12, 2021	May 14, 2020	Oct. 25, 2017
	Jun. 30, 2021	Jun. 30, 2020	Jun. 30, 2021	Jun. 30, 2020			
2017 Stock Incentive Plan							
Additional stock based compensation expense related to modification	\$ 12,790	\$ 51,000	\$ 26,239	\$ 51,000			
Remaining stock based compensation expense related to modification			\$ 109,000				
Shares available for grant under the 2017 Plan	585,772		585,772				
Stock option awards shares modified						203,750	
Common stock shares reserved for future issuance, one time increase					500,000		
Common stock shares reserved for future issuance							750,000
2017 Stock Incentive Plan January 1, 2020 [Member]							
Common stock shares reserved for future issuance, increase	102,540		102,540				
2017 Stock Incentive Plan January 1, 2021 [Member]							
Common stock shares reserved for future issuance, increase	102,998		102,998				
2017 Stock Incentive Plan From January 1, 2022 to January 1, 2027 [Member]							
Common stock shares reserved for future issuance, annual increase, percentage			1.0%				
Restricted Stock Units (RSUs) [Member]							
Stock-based compensation for stock options	\$ 18,112	\$ 10,912	\$ 38,567	\$ 10,912			
Restricted stock outstanding	2,964	15,686	2,964	15,686			
Restricted stock vested			15,686	0			
Employee Stock Option							
Stock Based compensation expense related to ESPP	\$ 1,844	\$ 1,991	\$ 12,295	\$ 11,993			
Expense Stock Options [Member]							
Future expenses		122,000		122,000			
Stock-based compensation for stock options	\$ 520,361	\$ 414,272	\$ 938,553	\$ 864,937			
Employee Stock Purchase Plan [Member]							
Remaining shares available for issuance	158,214		158,214				
Employee Stock Purchase Plan [Member] January 1, 2020 [Member]							
Common stock shares reserved for future issuance, increase	51,270		51,270				

[Employee Stock Purchase Plan \[Member\] | January 1, 2021 \[Member\]](#)

Common stock shares reserved for future issuance, increase	51,499	51,499
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[Employee Stock Purchase Plan \[Member\] | From January 1, 2022 to January 1, 2027 \[Member\]](#)

Common stock shares reserved for future issuance, annual increase, percentage		0.5%
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Debt (Details) - USD (\$) **Jun. 30, 2021 Dec. 31, 2020**

Debt

<u>Note payable</u>	\$ 15,000,000	
<u>Add: PIK interest (added to principal)</u>	93,397	
<u>Add: final fee</u>	675,000	
<u>Less: unamortized debt issuance costs</u>	(466,482)	
<u>Less: unamortized debt discount</u>	(1,068,847)	
<u>Total long-term debt</u>	\$ 14,233,068	\$ 0

Debt (Details 1)	Jun. 30, 2021
	USD (\$)
<u>Debt</u>	
<u>2024</u>	\$ 5,660,024
<u>2025</u>	7,546,698
<u>2026</u>	2,561,675
<u>Total long-term debt</u>	\$ 15,768,397

Debt (Details Narrative)	Apr. 08, 2021 USD (\$) \$ / shares shares
<u>Common stocks issued shares</u>	26,042
<u>Common stock Exercise price \$ / shares</u>	\$ 14.40
<u>Debt issuance costs</u>	\$ 500,000
<u>Lendor [Member]</u>	
<u>Agreed to pay loan</u>	25,000,000
<u>Security and Loan agreement [Member] Innovatus Life Sciences [Member]</u>	
<u>Term B loan to be funded before March 31, 2022</u>	5,000,000
<u>Non contingent term A loan, funded</u>	15,000,000.0
<u>Line of credit facility, maximum borrowing capacity</u>	25,000,000
<u>Term C loan to be funded before March 31, 2023</u>	\$ 5,000,000
<u>Common stock shares issuable upon exercise of warrants shares</u>	26,042
<u>Additional debt discount recognized</u>	\$ 300,000
<u>Term loans, interest rate</u>	11.36%
<u>Term loans, interest, payable in kind</u>	2.7%
<u>Non refundable facility fee payable to lender, percentage</u>	1.00%
<u>Final fee payable to lender, percentage</u>	4.50%
<u>Non refundable facility fee payable to lender, amount</u>	\$ 700,000
<u>Final fee payable to lender, amount</u>	\$ 100,000

License Agreement (Details

Narrative) - USD (\$) Apr. 08, 2021 Jun. 30, 2021

\$ in Millions

Subsequent Events

Milestone payments \$ 335.0

Upfront fees \$ 5.0

Common stock issued value \$ 5.0

Subsequent Events (Details Narrative) - \$ / shares	1 Months Ended 6 Months Ended	
	Feb. 26, 2021	Jun. 30, 2021
Issuance of common stock upon closing of follow-on offering, net shares July 1, 2021 [Member]	1,971,100	
Offering price for public offering		\$ 25.00
Issuance of common stock upon closing of follow-on offering, net shares		2,250,000

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5. The fifth part of the document contains a list of appendices, which include additional data, calculations, and supporting information.

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5. Discussion
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Table with multiple columns and rows, containing various data points and text. The table is mostly empty with some faint text visible in the left margin.

1. The first part of the document is a list of names and titles, including the names of the authors and the titles of the works. This list is organized into several columns and rows, with some entries appearing to be repeated or listed in multiple places. The text is very small and difficult to read, but it appears to be a formal list or index of some kind.

2. The second part of the document consists of a series of numbered entries, each followed by a short paragraph of text. These entries appear to be a list of items, possibly a bibliography or a list of references, with each item being identified by a number and a brief description. The text is again very small and difficult to read, but the structure suggests a list of items with associated information.

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2. The second part of the document outlines the various methods used to collect and analyze data. It includes a detailed description of the sampling process and the statistical techniques employed to ensure the reliability of the results.

3. The third part of the document presents the findings of the study. It highlights the key trends and patterns observed in the data, as well as the implications of these findings for the industry and the broader economy.

4. The fourth part of the document discusses the limitations of the study and suggests areas for future research. It acknowledges the potential biases and limitations of the data and the methods used, and offers suggestions for how these issues can be addressed in future studies.

5. The fifth part of the document provides a conclusion and a summary of the main points. It reiterates the importance of accurate record-keeping and the need for ongoing research in this field.

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6. The sixth part of the document includes a list of references and a bibliography. It cites the various sources used in the study and provides information on how to access them.

7. The seventh part of the document contains a list of appendices and supplementary materials. These include additional data, charts, and tables that provide further detail on the study's findings.

8. The eighth part of the document is a glossary of terms and definitions. It provides clear and concise explanations of the key concepts and terminology used throughout the document.

9. The ninth part of the document is a list of acknowledgments. It expresses gratitude to the individuals and organizations that provided support and assistance during the course of the study.

10. The tenth part of the document is a list of contact information for the authors and the research team. It provides details on how to reach them for further information or inquiries.

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