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 March 31, 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	**No. 82-2863566**
(State of incorporation)	**(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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

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

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

On May 3, 2021 there were 12,647,037 shares of the registrant's common stock, $0.001 par value per share, outstanding.

Celcuity Inc.
Table of Contents

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

PART I. FINANCIAL INFORMATION

ITEM 1. Financial Statements

Celcuity Inc.
Condensed Balance Sheets

	March 31, 2021 (unaudited)	December 31, 2020
Assets		
Current Assets:		
Cash and cash equivalents	$ 34,936,902	$ 11,637,911
Deposits	22,009	22,009
Deferred transaction costs	13,719	-
Payroll tax receivable	190,000	190,000
Prepaid assets	551,345	317,040
Total current assets	35,713,975	12,166,960
Property and equipment, net	466,484	558,876
Operating lease right-of-use assets	186,602	230,911
Total Assets	$ 36,367,061	$ 12,956,747
Liabilities and Stockholders' Equity:		
Current Liabilities:		
Accounts payable	$ 318,213	$ 217,377
Finance lease liabilities	5,819	5,810
Operating lease liabilities	185,656	187,518
Accrued expenses	660,849	774,612
Total current liabilities	1,170,537	1,185,317
Finance lease liabilities	6,841	8,299
Operating lease liabilities	15,139	60,861
Total Liabilities	1,192,517	1,254,477
Stockholders' Equity:		
Preferred stock, $0.001 par value: 2,500,000 shares authorized; 0 shares issued and outstanding as of March 31, 2021 and December 31, 2020	-	-
Common stock, $0.001 par value: 25,000,000 shares authorized; 12,287,896 and 10,299,822 shares issued and outstanding as of March 31, 2021 and December 31, 2020, respectively	12,288	10,300
Additional paid-in capital	64,275,505	38,013,551
Accumulated deficit	(29,113,249)	(26,321,581)
Total Stockholders' Equity	35,174,544	11,702,270
Total Liabilities and Stockholders' Equity	$ 36,367,061	$ 12,956,747

See accompanying notes to the financial statements

Celcuity Inc.
Condensed Statements of Operations
(unaudited)

	Three Months Ended March 31,	
	2021	**2020**
Operating expenses:		
Research and development	$ 2,236,342	$ 1,847,414
General and administrative	555,428	463,399
Total operating expenses	2,791,770	2,310,813
Loss from operations	(2,791,770)	(2,310,813)
Other income (expense)		
Interest expense	(24)	(33)
Interest income	388	63,851
Loss on sale of fixed assets	(263)	-
Other income, net	101	63,818
Net loss before income taxes	(2,791,668)	(2,246,995)
Income tax benefits	-	-
Net loss	$ (2,791,668)	$ (2,246,995)
Net loss per share, basic and diluted	$ (0.25)	$ (0.22)
Weighted average common shares outstanding, basic and diluted	11,072,097	10,253,988

See accompanying notes to the financial statements

Celcuity Inc.
Condensed Statements of Changes in Stockholders' Equity
Three Months Ended March 31, 2021

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total
	Shares	Amount			
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)*	12,287,896	$ 12,288	$ 64,275,505	$ (29,113,249)	$ 35,174,544

See accompanying notes to the financial statements

Celcuity Inc.
Condensed Statements of Changes in Stockholders' Equity
Three Months Ended March 31, 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

See accompanying notes to the financial statements

Celcuity Inc.
Condensed Statements of Cash Flows
(unaudited)

	Three Months Ended March 31,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (2,791,668)	$ (2,246,995)
Adjustments to reconcile net loss to net cash used for operations:		
Depreciation	98,222	94,792
Stock-based compensation	449,098	464,649
Loss on sale of fixed assets	263	-
Changes in operating assets and liabilities:		
Prepaid assets and deposits	(234,305)	(62,651)
Accounts payable	73,924	(92,197)
Accrued expenses	(113,763)	30,143
Non-cash operating lease, net	(3,276)	(21,342)
Net cash used for operating activities	(2,521,505)	(1,833,601)
Cash flows from investing activities:		
Purchases of property and equipment	(30,925)	(45,604)
Proceeds from sale of property and equipment	500	-
Net cash used for investing activities	(30,425)	(45,604)
Cash flows from financing activities:		
Proceeds from exercise of common stock warrants	11,257	-
Proceeds from follow-on offering, net of underwriting discounts and offering costs	25,814,167	-
Gross proceeds from an ATM offering	38,962	-
Payments for secondary registration statement costs	(12,016)	-
Payments for finance leases	(1,449)	(1,438)
Net cash provided by (used for) financing activities	25,850,921	(1,438)
Net change in cash and cash equivalents	23,298,991	(1,880,643)
Cash and cash equivalents:		
Beginning of period	11,637,911	18,735,002
End of period	$ 34,936,902	$ 16,854,359
Supplemental disclosures of non-cash investing and financing activities:		
Property and equipment included in accounts payable	$ -	$ 14,101
Offering and registration statement costs included in accounts payable	$ 51,245	$ 6,127

See accompanying notes to the financial statements

CELCUITY INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS (unaudited)
(For the Three Months Ended March 31, 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.

2. 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 months ended March 31, 2021 are not necessarily indicative of the results to be expected during the remainder of the current year or for any future period.

Follow-on Offering

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.

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.

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 months ended March 31, 2021 and 2020, potentially dilutive securities excluded from the computations of diluted weighted-average shares outstanding were options to purchase 855,072 and 630,889 shares of common stock, respectively, warrants to purchase 352,400 and 353,585 shares of common stock, respectively, and 15,686 and 0 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.

Supplemental balance sheet information consisted of the following at March 31, 2021:

Operating Lease		
Right-of-use assets	$	186,602
Operating lease liability	$	200,795
Less: short term portion		(185,656)
Long term portion	$	15,139
Finance Lease		
Furniture and equipment	$	28,932
Less: Accumulated depreciation		(16,395)
Net book value of property and equipment under finance lease	$	12,537
Finance lease liability	$	12,660
Less: short term portion		(5,819)
Long term portion	$	6,841

Maturity analysis under lease agreements consisted of the following as of March 31, 2021:

	Operating Leases	Finance Leases
2021	$ 146,116	$ 5,441
2022	64,940	7,255
2023	-	3,023
Total minimum lease payments	211,056	15,719
Less: Present value discount	(10,261)	(99)
Less: Amount representing services	-	(2,960)
Present value of net minimum lease payments	$ 200,795	$ 12,660

Weighted Average	Remaining Lease Term	Discount Rate
Operating lease	1.1 years	4.0%
Finance lease	2.1 years	1.0%

Lease costs for the period ended March 31, 2021:

	Three-month Period
Operating lease cost	$ 45,430
Finance lease cost:	
Amortization	1,447
Interest	24
Variable lease cost	19,869
	$ 66,770

Supplemental cash flow information related to leases for the period ended March 31, 2021:

	Three-month Period
Cash paid for amounts included in operating and finance leases:	
Operating cash outflow from operating leases	$ 68,574
Operating cash outflow from finance leases	24
Financing cash outflow from finance leases	1,449
	$ 70,047

Clinical Research Studies

In May 2017, the Company entered into an agreement with a clinical research organization to conduct a clinical research study. The Company made payments of approximately $275,000 and $100,000 in 2021 and 2020, respectively, and $600,000 prior to 2020. Additional payments will be due as certain milestones are met and clinical sites are added. The maximum amount of these additional payments is estimated to be approximately $2,340,000 over the course of the agreement.

In October 2018, the Company entered into an agreement with a biopharmaceutical company and a cancer research center to conduct a clinical research study. The Company made payments of approximately $70,000 prior to 2020. Additional payments of approximately $112,000 will be due as certain milestones are met.

In December 2020, the Company entered into an agreement with a biopharmaceutical company and a cancer research center to conduct a clinical research study. The Company made zero payments in 2021 and 2020. Future payments of approximately $740,000 will be due as certain milestones are met.

In January 2021, the Company entered into an agreement with a biopharmaceutical company and a cancer research center to conduct a clinical research study. The Company made zero payments in 2021. Future payments of approximately $1,210,600 will be due as certain milestones are met.

In March 2021, the Company entered into an agreement with two biopharmaceutical companies and a cancer research center to conduct a clinical research study. The Company made zero payments in 2021. Future payments of approximately $1,548,000 will be due as certain milestones are met.

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 three months ended March 31, 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 three months ended March 31:

	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	38,391	15.20	57,500	10.17
Exercised	29,997	8.00	-	-
Forfeited	(3,271)	7.62	(11,826)	10.60
Balance at March 31	855,072	$ 9.65	630,889	$ 14.06
Options exercisable at March 31:	406,332	$ 10.37	274,267	$ 9.65
Weighted Average Grant Date Fair Value for options granted during the period:		$ 10.07		$ 6.59

The following table summarizes additional information about stock options outstanding and exercisable at March 31, 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
855,072	7.81	$ 9.65	$ 5,179,019	406,332	$ 10.37	$ 2,325,179

The Company recognized stock-based compensation expense for stock options of $418,192 and $450,664 for the three months ended March 31, 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 $13,449 and $0 for the three months ended March 31, 2021 and 2020, respectively. The effect on stock-based compensation over the remaining service period will be approximately $122,000.

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 three months ended March 31:

	2021	2020
Risk-free interest rate	0.63% - 1.12%	1.35% - 1.66%
Expected volatility	76.6%	73.3%
Expected life (years)	5.0 to 6.07	5.5 to 6.1
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.

No restricted stock awards were granted during the three months ended March 31, 2021 and 2020. The Company had 15,686 and 0 shares of restricted stock outstanding as of March 31, 2021 and 2020, respectively, and 0 shares of restricted stock vested during the three months ended March 31, 2021 or 2020. The Company recognized stock-based compensation expense for restricted stock of $20,456 and $0 for the three months ended March 31, 2021 and 2020, respectively.

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. 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 March 31, 2021 was 266,800.

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

2021	$ 1,032,220
2022	1,147,153
2023	789,853
2024	291,273
2025	11,616
Total estimated compensation cost to be recognized	$ 3,272,115

The Company recognized stock-based compensation expense related to its employee stock purchase plan of $10,450 and $13,985 for the three months ended March 31, 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 March 31, 2021 was 163,710.

The Company recognized total stock-based compensation expense as follows for the three months ended March 31:

	Three Months Ended	
	2021	2020
Stock-based compensation expense in operating expenses:		
Research and development	$ 255,181	$ 293,116
General and administrative	193,917	171,533
Total	$ 449,098	$ 464,649

7. Subsequent Events

On April 8, 2021, the Company entered into a license agreement (the "License Agreement") with Pfizer, Inc. ("Pfizer"), pursuant to which the Company acquired exclusive (including as to Pfizer) worldwide sublicensable rights 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. Pursuant to the License Agreement, the Company is obligated to use commercially reasonable efforts to develop and seek regulatory approval for at least one product in the United States and if regulatory approval is obtained, to commercialize such product in the United States and at least one international major market.

The Company paid Pfizer a $5.0 million upfront fee upon execution of the License Agreement and, pursuant to an Equity Grant Agreement, issued to Pfizer $5.0 million of shares of the Company's common stock. The number of shares issued was 349,406 and was calculated by dividing $5.0 million by $14.31, the closing price of a share of the Company's common stock on the Nasdaq Capital Market on April 8, 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 $330.0 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.

Also, 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"), as collateral agent and the Lenders listed on Schedule 1.1 thereto, pursuant to which Innovatus, as a Lender, has agreed to make certain term loans to the Company in the aggregate principal amount of up to $25.0 million (the "Term Loans").

Funding of the first $15.0 million tranche occurred on April 8, 2021. The Company will be eligible to draw on a second tranche of $5.0 million upon achievement of certain milestones, including meeting the primary end points of either the FACT-1 or FACT-2 clinical trials and receipt of unrestricted net cash proceeds of at least $50.0 million from the issuance and sale of the Company's equity securities. The Company will be eligible to draw on a third tranche of $5.0 million upon the achievement of certain additional milestones, including commencement of certain Phase 3 clinical trials and the receipt of unrestricted net cash proceeds of at least $75.0 million from the issuance and sale of the Company's equity securities.

Innovatus 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").

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%. Additionally, the Company elected to make 2.7% of the interest rate as payable in-kind, which shall accrue as principal monthly. Other fees include a 1.0% facility fee on the funded loan amount, paid at closing and a final fee of 4.5% of the funded loan amount due at the maturity date or earlier if the Company prepays the loan. 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.

The Loan Agreement is secured by all assets of the Company. Proceeds will be used for working capital purposes and to fund the Company's general business requirements. The Loan Agreement contains customary representations and warranties and covenants, subject to customary carve outs, and includes financial covenants related to liquidity and trailing twelve months revenue.

In connection with each funding of the Term Loans, the Company is required to issue to Innovatus a warrant (the "Warrants") to purchase a number of shares of the Company's common 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) 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 or (ii) the closing price on the last trading day immediately preceding the execution of the Loan Agreement. For the second and third tranches only the exercise price will be based on the lower of (i) the exercise price for the first tranche or (ii) 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 relevant Term Loan funding. The Warrants may be exercised on a cashless basis and are exercisable through the 10^{th} anniversary of the applicable funding date. The number of shares of common stock for which each Warrant is exercisable and the associated exercise price are subject to certain proportional adjustments as set forth in such Warrant.

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 pursing 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.

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.

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.

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 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.

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 15,000 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 initiated discussions with pharmaceutical companies about collaborating on clinical trials in late 2020.

We also made significant progress in 2020 developing a new CELsignia test intended to diagnose cancers driven by dysregulated RAS signaling. Dysregulation of RAS signaling, which includes the RAF/MEK/ERK and PI3K/AKT/mTOR pathways, is estimated to drive 30%-40% of all cancers. Pharmaceutical companies have developed numerous drugs that target RAS-involved pathways. However, the number of interactions amongst RAS-regulated pathways has made it extremely difficult to use molecular tests to identify patients with dysregulated RAS signaling tumors. The challenge of diagnosing a cancer driven by a dysregulated RAS signaling network is magnified because two or more different pathways are typically involved. Recent research has also found that RAS mutations play a much less important role in dysregulated RAS signaling than previously thought. Our CELsignia platform is uniquely suited to untangle the complexity of dysregulated RAS signaling tumors and identify the targeted therapy combination capable of treating it.

Once development of the new RAS test is completed, we intend to add it to our current CELsignia MP Test for breast and ovarian cancer. This next generation CELsignia test would provide an analysis of EGFR/HER1, HER2, HER3, c-MET, PI3K, and RAS-involved signaling activity for each patient tumor specimen received.

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. We are collaborating with Genentech, Pfizer, Novartis, and Puma to conduct five Phase 2 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. Our CELsignia MP Test analyzes HER2, c-MET, and PI3K signaling activity using a patient's live tumor cells. These tests have the potential to diagnose oncogenic signaling activity undetectable by molecular tests in up to one in three HER2-negative breast cancer patients and one in five ovarian cancer patients. We intend to use this test to identify HER2-negative breast cancer patients whose tumors have either abnormal HER2 signaling, abnormal c-Met and HER2 signaling, or abnormal PI3K signaling. Our overall commercialization strategy for our CELsignia CDx is to collaborate with pharmaceutical companies to advance the clinical development of their targeted therapies with the eventual goal of obtaining FDA approval of a new drug indication.

Our current programs include:

- Herceptin® and Perjeta® for HER2-negative early-stage breast cancer patients. Each drug targets the HER2 receptor and is owned by Genentech, Inc. These drugs are only currently approved to treat cancer patients who are HER2+.
- Vizimpro® and Xalkori® for HER2-negative late-stage breast cancer patients. Vizimpro, a pan-HER inhibitor, and Xalkori, a c-Met inhibitor, are owned by Pfizer, Inc. These drugs are currently only approved to treat patients with non-small cell lung cancer who have specific molecular mutations.
- Tabrecta® and Nerlynx® for HER2-negative late-stage breast cancer patients. Tabrecta, a c-Met inhibitor, is owned by Novartis AG and Nerlynx is owned by Puma Biotechnology, Inc. Tabrecta is currently only approved to treat patients with non-small cell lung cancer who have specific molecular mutations. Nerlynx is currently only approved to treat HER2+ breast cancer patients.
- Nerlynx and Faslodex for ER+/HER2-negative late-stage breast cancer patients. Faslodex, a selective estrogen receptor degrader, is owned by AstraZeneca.
- Nerlynx for ER-/HER2- early-stage breast cancer patients.

Interventional Clinical Trials in Process using a CELsignia Test to Select Patients for Treatment

FACT-1 Clinical Trial to Evaluate Efficacy of Genentech's HER2 Targeted Therapies

We are collaborating with NSABP and 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. NSABP serves as the sponsor and principal investigator of the trial and is responsible for, among other things, setting up clinical sites, enrolling patients, and managing clinical data. NSABP contracted separately with Genentech to provide Herceptin and Perjeta for the study at no cost. We are performing the CELsignia HER2 Pathway Activity Test to select patients for the trial and are providing the funding for the trial's patient-related costs. Completing this trial will require, among other things, successful enrollment of patients, meeting trial endpoint goals, and completing the trial in a timely manner. As of February 2021, there were 27 activated sites participating in the FACT-1 trial. The enrollment rate of patients has fallen short of the expectations NSABP originally provided. Based on NSABP's updated estimates of patient enrollment rates to reflect the impact of COVID-19, we expect to obtain interim results 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.

A synopsis of the trial protocol is provided below.

FACT-1 Clinical Trial Synopsis

Primary Objective	To evaluate the efficacy of neoadjuvant HER2 drug treatment in early-stage HER2-negative breast cancer patients with abnormal HER2 signaling
Sites/Sponsor	Multi-center in collaboration with NSABP and Genentech
Subjects	54 HER2-negative early-stage breast cancer (26 ER+/28ER-)
Endpoint	Pathological complete response (ypT0/Tis ypN0)
Investigational Arm	AC-T + Trastuzumab + Pertuzumab

FACT-2 Clinical Trial to Evaluate Efficacy of Puma's HER2 Targeted Therapy

We are collaborating with 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. West Cancer Center serves as the sponsor and principal investigator of the trial and is responsible for enrolling patients and managing clinical data. Puma supplies Nerlynx, its pan-HER inhibitor currently approved by the FDA for extended adjuvant treatment of early-stage HER2-positive breast cancer. We provide the CELsignia HER2 Pathway Activity Test to select triple-negative breast cancer patients who have hyperactive HER2-driven signaling pathways for the trial and will initially fund the patient-related trial costs. Based on West Cancer Center estimates to reflect the impact of COVID-19, we expect interim results from this trial 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. We believe there is significant clinical interest in finding new diagnostic tests and targeted therapies for triple-negative breast cancer patients because fewer drug treatment options are available to them relative to other breast cancer sub-types.

A synopsis of the trial protocol is provided below.

FACT-2 Clinical Trial Synopsis

Primary Objective	To evaluate the efficacy of neoadjuvant HER2 drug treatment in early-stage triple-negative breast cancer patients with abnormal HER2 signaling
Sites/Sponsor	Multi-center in collaboration with West Cancer Center and Puma
Subjects	27 early-stage triple-negative breast cancer with abnormal HER2 signaling
Endpoint	Pathological complete response (ypT0/Tis ypN0)
Investigational Arm	Neratinib then Paclitaxel + Carboplatin + Neratinib

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, a global leader in cancer research, and Pfizer Inc., a global biopharmaceutical company, 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. Under the agreement, Sarah Cannon will serve as the sponsor and principal investigator of the trial and will be responsible for enrolling patients and managing clinical data. Pfizer will supply Vizimpro and Xalkori, targeted therapies currently approved by the FDA to treat metastatic non-small cell lung cancer. We will provide our CELsignia Multi-Pathway Activity Test to select HER2- metastatic breast cancer patients who have hyperactive HER2 and c-Met signaling pathways for the trial and will fund the patient-related trial costs. Based on the Sarah Cannon Research Institute's estimates of patient enrollment rates, we expect to obtain interim results 12 to 15 months after the protocol is activated and final results 12-15 months later. We expect enrollment to begin in the second or 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. We believe there is significant clinical interest in finding new diagnostic tests and targeted therapies for metastatic HER2-negative breast cancer patients whose disease progressed on prior therapies. The anti-tumor effect of blockading EGFR/HER1, HER2, HER3 and c-Met pathways when the HER2 and c-Met pathways are hyperactive has been demonstrated in animal models.

A synopsis of the trial protocol is provided below.

FACT-3 Clinical Trial Synopsis

Primary Objective	To assess the efficacy of combined Vizimpro plus Xalkori in previously treated HER2-negative metastatic breast cancer subjects with hyperactive HER2 and c-Met signaling tumors
Sites/Sponsor	Multi-center in collaboration with Sarah Cannon Research Institute and Pfizer
Subjects	23 late-stage HER2-negative breast cancer with abnormal HER2/c-Met signaling
Endpoint	Objective response using RECIST 1.1 criteria
Investigational Arm	Vizimpro and 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 Biotechnology, 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. Under the agreement, Massachusetts General Hospital will serve as the sponsor and the principal investigator of this study, while the UCLA Jonsson Comprehensive Cancer Center and the Vanderbilt-Ingram Cancer Center will serve as co-sponsors. Each of these institutions is amongst the United States' 51 NCI-Designated Comprehensive Cancer Centers tasked with developing new approaches to diagnosing and treating cancer. Puma will supply Nerlynx, its HER2 inhibitor currently approved by the FDA for early and late-stage HER2-positive breast cancer. We will provide our CELsignia HER2 Pathway Activity Test to select HR+, HER2-negative metastatic breast cancer patients who have hyperactive HER2-driven signaling pathways for the trial and will fund the patient-related trial costs. Based on Massachusetts General Hospital's estimates of patient enrollment rates, we expect to obtain interim results 12 to 15 months after the protocol is activated and final results 12 to 15 months later. We expect enrollment to begin in the second 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. We believe there is significant clinical interest in finding new diagnostic tests and targeted therapies for metastatic HR+, HER2-negative breast cancer patients whose disease progressed on prior therapies. Of particular interest are new therapeutic combinations that can overcome resistance to anti-estrogen therapies like Faslodex. The blockade of estrogen receptor and HER2 pathways when the HER2 pathway is hyperactive using a combination of Neratinib and Faslodex has been demonstrated in animal models.

A synopsis of the trial protocol is provided below.

FACT-4 Clinical Trial Synopsis

Primary Objective	To assess the efficacy of combining Nerlynx plus Faslodex in previously treated metastatic HR-positive, HER2-negative patients with hyperactive HER2 signaling tumors
Sites/Sponsor	Multi-center in collaboration with Mass General and Puma
Subjects	23 late-stage HR+/HER2-negative breast cancer with abnormal HER2 signaling
Endpoint	Objective response using RECIST 1.1 criteria
Investigational Arm	Nerlynx and Faslodex

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, a global leader in cancer research, Novartis AG, a global biopharmaceutical company, and Puma Biotechnology, 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. Under the agreement, MD Anderson will serve as the sponsor of the trial and will be responsible for enrolling patients and managing clinical data. Novartis will supply Tabrecta, a targeted therapy currently approved by the FDA to treat metastatic non-small cell lung cancer. Puma will supply Nerlynx, a targeted therapy currently approved by the FDA to treat HER2+ metastatic breast cancer. We will provide our CELsignia Multi-Pathway Activity Test to select HER2- metastatic breast cancer patients who have hyperactive HER2 and c-Met signaling pathways for the trial and will fund the patient-related trial costs. Based on MD Anderson's estimates of patient enrollment rates, we expect to obtain interim results 12 to 15 months after the protocol is activated and final results 12-15 months later. We expect enrollment to begin in the second or 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. We believe there is significant clinical interest in finding new diagnostic tests and targeted therapies for metastatic HER2-negative breast cancer patients whose disease progressed on prior therapies. The anti-tumor effect of blockading EGFR/HER1, HER2, HER3 and c-Met pathways when the HER2 and c-Met pathways are hyperactive has been demonstrated in animal models.

A synopsis of the trial protocol is provided below.

FACT-6 Clinical Trial Synopsis

Primary Objective	To assess the efficacy of combined Tabrecta plus Nerlynx in previously treated HER2-negative metastatic breast cancer subjects with hyperactive HER2 and c-Met signaling tumors
Sites/Sponsor	Multi-center in collaboration with MD Anderson, Novartis, and Puma
Subjects	Up to 48 late-stage HER2-negative breast cancer with abnormal HER2/c-Met signaling
Endpoint	Objective response using RECIST 1.1 criteria
Investigational Arm	Tabrecta and Nerlynx

In conjunction with the development of our CELsignia tests, 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 U.S. Food and Drug Administration ("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 patients selected with one of our CELsignia tests. We are currently evaluating, or expect to evaluate, a variety of targeted therapies in combination with other targeted therapies, hormonal therapies, of chemotherapies, including: i) pan-HER and c-Met inhibitors; ii) pan-HER inhibitors and endocrine therapy; iii) pan-HER inhibitors and chemotherapies; and iv) PI3K inhibitors and endocrine therapy. The FDA has approved three c-Met inhibitors, six HER-family inhibitors, and four PI3K inhibitors for cancer treatment. Additional c-Met, HER-family, and PI3K inhibitors are being evaluated in on-going clinical trials.

Gedatolisib – An Internal Drug Candidate

Overview

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 on Breast Cancer and Current Treatments

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. These drugs generated revenues of nearly $10 billion globally in 2019.

Endocrine-based therapies. Selective ER modulators (tamoxifen), selective ER degrader (fulvestrant), and aromatase inhibitors (AIs) are established standards of care in women with HR+/HER2- mBC. The choice between these regimens when treating mBC depends on the type and duration of prior endocrine therapy treatment as well as the time elapsed from the end of prior endocrine therapy. Besides the well-known efficacy of these treatments as first-line therapies in women without visceral crisis, most patients develop endocrine resistance leading to therapeutic failure. Primary endocrine resistance is defined as relapse during the first two years of prior endocrine therapy or progressive disease within the first six months of first-line endocrine therapy for mBC. Secondary resistance is present (1) when a relapse occurs after the first two years of adjuvant endocrine therapy; (2) when a relapse occurs within 12 months of completing adjuvant endocrine therapy; or (3) when a progressive disease occurs after more than six months from the beginning of endocrine therapy for mBC.

Several mechanisms are responsible for endocrine resistance, including the dysregulation of multiple components of the ER pathway (aberration in ER expression, over-expression of ER co-activators, and down-regulation of co-repressors), altered regulation of signaling molecules involved in cell cycle or cell survival, and the activation of escape pathways that can provide cell replication.

CDK4/6 inhibitors. One common mechanism of resistance to endocrine therapies is the activation of the cyclin-dependent kinases 4 and 6 (CDK4/6) pathway. These kinases drive cell cycle progression and division. Inhibiting activation of the CDK4/6 prevents estrogen from activating the cyclin D1-CDK4/6-Rb complex, thus blockading an important mechanism of resistance to endocrine therapies. The resulting cell cycle arrest induces a significant delay in tumor progression.

CDK 4/6 inhibitors were first introduced in 2015. Endocrine therapies administered in combination with oral CDK4/6 inhibitors lead to improved clinical efficacy when compared with endocrine therapies as monotherapy. In two randomized, double-blind clinical trials, treatment of HR+/HER2- advanced breast cancer patients with a combination of palbociclib and either letrozole or fulvestrant demonstrated a significant increase in the median progression free survival (PFS) period for patients who received palbociclib in combination with either letrozole or fulvestrant compared to patients who received letrozole or fulvestrant as single agents. These patients had previously progressed on or after prior endocrine therapy. Worldwide sales of currently marketed CDK4/6 inhibitors, which are indicated for the treatment of breast cancer, were $6.0 billion in 2019, and are expected to grow to $14.4 billion in 2026. Worldwide sales of Pfizer's leading CDK4/6 inhibitor, palbocicib, or Ibrance®, were $5.4 billion in 2020.

PI3K inhibitors. Another common mechanism of resistance to endocrine inhibitors is the activation of the PI3K pathway, an important intracellular pathway that regulates cell growth and metabolism. Approximately one third of HR+ breast cancer tumors resistant to endocrine therapy harbor activating mutations of the catalytic subunit of PI3K, referred to as PIK3CA. Fulvestrant used in combination with alpelisib, an oral PI3K-α inhibitor marketed as Piqray® by Novartis approved by the FDA in May 2019, has demonstrated improved clinical efficacy in patients whose tumors had a PIK3CA mutation and had not yet received treatment with a CDK4/6 inhibitor. These patients had previously progressed on or after prior endocrine therapy. Worldwide sales of Piqray®, currently the only FDA-approved for the treatment of breast cancer, limited to patients with PIK3CA mutations, were approximately $320.0 million in 2020.

mTOR inhibitors. Similar to CDK4/6 and PI3K, the mTOR pathway has also been identified as a mechanism of resistance to endocrine therapy. Everolimus is an mTOR inhibitor that is currently approved by the FDA for the treatment of HR+/HER2- advanced breast cancer in combination with exemestane, an AI. Everolimus has also shown clinical benefit in combination with fulvestrant. These patients had previously progressed on or after prior AI therapy. Worldwide sales in breast cancer of everolimus, marketed as Afinitor® by Novartis and a leading mTOR inhibitor, were approximately $831.0 million in 2019.

The Importance of Targeting PI3K and mTOR in Cancer

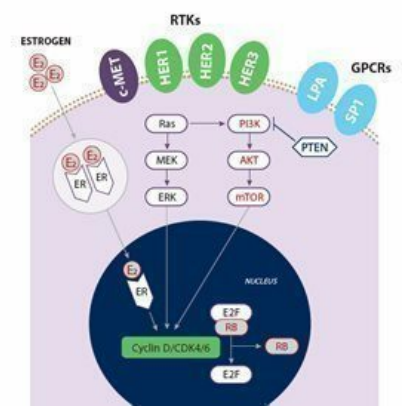
Activation of the PI3K/mTOR pathway has been implicated in a wide variety of human cancers, involving either activating mutations, or other unknown drivers of pathway amplification. These include cancers of the breast, prostate, endometrial, colon, rectum, and lung, among others.

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 (p110α, p110β, p110δ, or p110γ) and a regulatory (p85α, p55α, p50α, p85β, p55γ, 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 p110α catalytic isoform is necessary for the growth of tumors driven by PIK3CA mutations and/or oncogenic RAS and receptor tyrosine kinases; the p110β catalytic isoform mediates tumorigenesis arising from the loss of the dephosphorylase activity of PTEN; and the p110δ 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, GSK3β, 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.

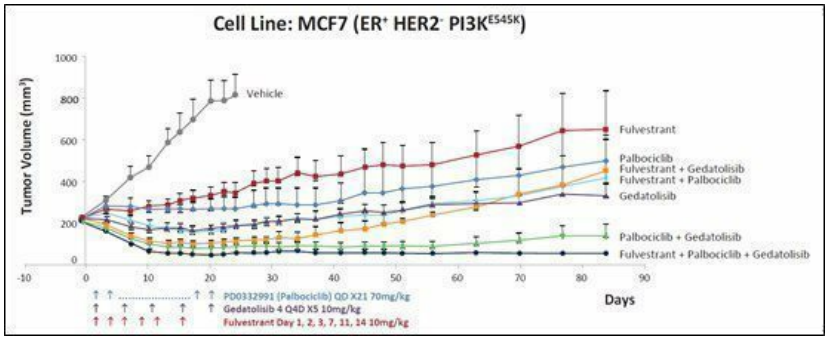
The illustration below depicts the PI3K/AKT/mTOR pathway and various pathway activation mechanisms.



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.

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 p110α, p110β, p110γ, and p110δ 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 repeatably 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 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.

Clinical Experience with Gedatolisib

As of January 11, 2021, 457 patients with solid tumors have received gedatolisib in eight clinical trials sponsored by Pfizer. Of the 457 patients, 129 were treated with gedatolisib as a single agent in three clinical trials. The remaining 328 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

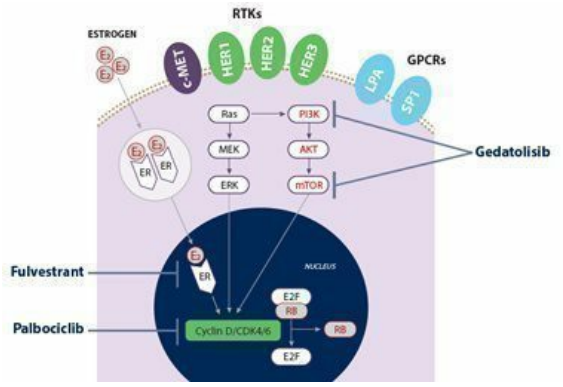
Pfizer conducted a Phase 1, open-label, dose-escalation first-in human study of single-agent gedatolisib in patients with advanced solid tumors. The primary objective of Part 1 of the study was to determine the safety, tolerability, and maximum tolerated dose (MTD) of single-agent gedatolisib administered 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 ALT (7.1%), and increased 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.



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

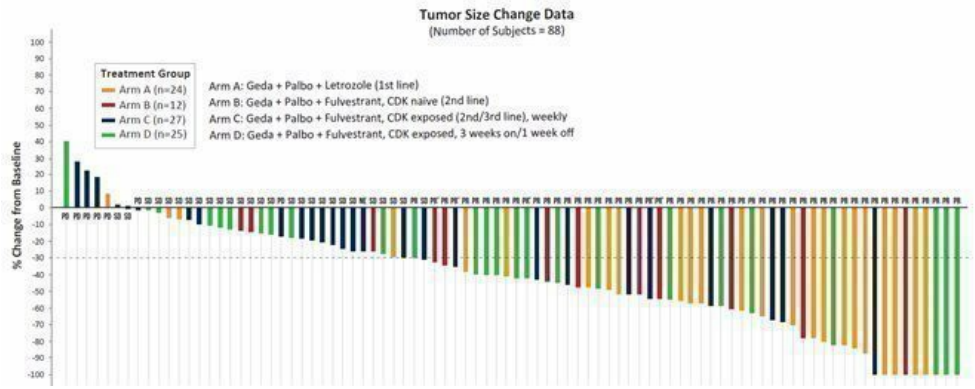
- 35 patients were enrolled in two dose escalation arms to evaluate the safety and tolerability and determine the MTD of gedatolisib when used in combination with the standard doses of palbociclib and endocrine therapies. The MTD was determined to be 180 mg administered intravenously once weekly.

- 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).



- 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%), dysegeusia (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.

- 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)**	84%	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.

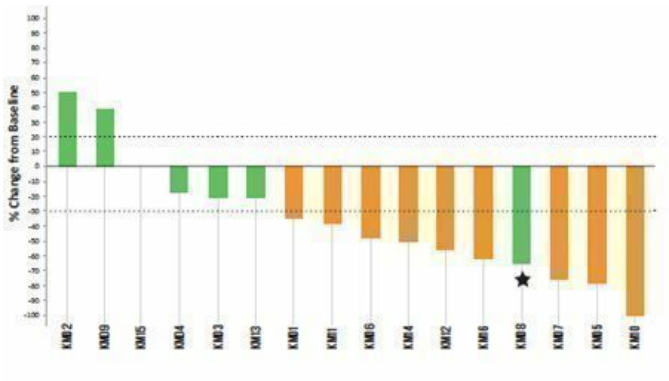
We expect to use the CELsignia PI3K activity test to help support development of gedatolisib for breast cancer indications. Our internal studies demonstrate how measurement of PI3K-involved signaling may provide a sensitive and specific method of identifying patients most likely to benefit from PI3K 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 pursing 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.

Phase 2 Pilot Clinical Trial for HER2+/PIK3CA+ Patients

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).

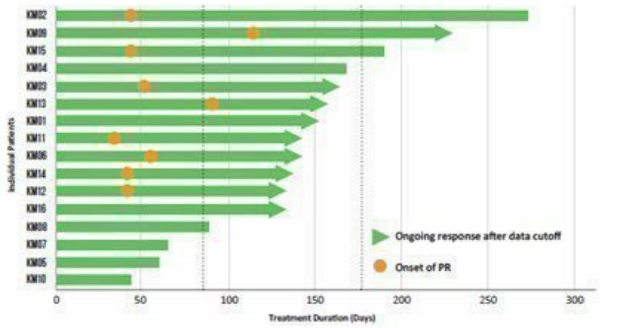
Best Response



* 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 20 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 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. 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. In addition, cancer research-related industry meetings, such as the American Association for Cancer Research (AACR), were delayed for several months. Our submissions to present research results at these meetings were accepted, but the release of the results were postponed in conjunction with the delayed meeting schedules.

Liquidity

Although there is uncertainty related to the anticipated impact of the recent COVID-19 outbreak on our future results, we believe our existing balance of cash and cash equivalents will be sufficient to meet our cash needs arising in the ordinary course of business for at least the next twelve months.

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 March 31, 2021 and 2020, we reported a net loss of approximately $2.8 million and $2.2 million, respectively. As of March 31, 2021, we had an accumulated deficit of approximately $12.6 million under Celcuity LLC and $29.1 million under Celcuity Inc. As of March 31, 2021, we had cash and cash equivalents of approximately $34.9 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 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 the result of finance lease obligations.

Interest Income

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

Results of Operations

	Three Months Ended March 31,		Increase (Decrease)	
	2021	2020	$	Percent Change
Statements of Operations Data:				
Operating expenses:				
Research and development	$ 2,236,342	$ 1,847,414	$ 388,928	21%
General and administrative	555,428	463,399	92,029	20
Total operating expenses	2,791,770	2,310,813	480,957	21
Loss from operations	(2,791,770)	(2,310,813)	(480,957)	21
Other income (expense)				
Interest expense	(24)	(33)	10	n/a
Interest income	388	63,851	(63,463)	(99)
Loss on sale of fixed assets	(263)	-	(263)	n/a
Other income, net	101	63,818	(63,716)	(100)
Net loss before income taxes	(2,791,668)	(2,246,995)	(544,673)	24
Income tax benefits	-	-	-	-
Net loss	$ (2,791,668)	$ (2,246,995)	$ (544,673)	24%

Research and Development

Our research and development expenses for the three months ended March 31, 2021 were approximately $2.24 million, representing an increase of approximately $0.39 million, or 21%, compared to the same period in 2020. The increase primarily resulted from a $0.06 million increase in compensation related expenses, which included a decrease of approximately $0.04 million of non-cash stock-based compensation, to support development of our CELsignia platform. In addition, other research and development expenses increased $0.33 million due to clinical validation and laboratory studies, 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.

General and Administrative

Our general and administrative expenses for the three months ended March 31, 2021 were approximately $0.56 million, representing an increase of approximately $0.09 million, or 20%, compared to the same period in 2020. The increase primarily resulted from a $0.08 million increase in 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, an expanding infrastructure, and increased professional fees associated with being a public company.

Interest Expense

Interest expense for the three months ended March 31, 2021 is related to finance lease liabilities.

Interest Income

Interest income for the three months ended March 31, 2021 was minimal and represents a decrease of approximately $0.06 million or 99% 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 March 31, 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 March 31, 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.

Cash from these capital raising activities has been our primary source of funds for our operations since inception. As of March 31, 2021, our cash and cash equivalents were approximately $34.9 million, and we had an accumulated deficit of approximately $12.6 million under Celcuity LLC and approximately $29.1 million under Celcuity Inc.

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

	Three Months Ended March 31,	
	2021	**2020**
	(unaudited)	
Net cash provided by (used in):		
Operating activities	$ (2,521,505)	$ (1,833,601)
Investing activities	(30,425)	(45,604)
Financing activities	25,850,921	(1,438)
Net increase (decrease) in cash and cash equivalents	$ 23,298,991	$ (1,880,643)

Operating Activities

Net cash used in operating activities was approximately $2.52 million for the three months ended March 31, 2021 and consisted primarily of a net loss of approximately $2.79 million and working capital changes of approximately $0.28 million, adjusted for non-cash expense items of approximately $0.55 million. The approximately $0.28 million of working capital changes was primarily due to an increase in prepaid assets and a decrease in accrued expenses. Non-cash expense items of approximately $0.55 million primarily consisted of depreciation expense of $0.10 million and $0.45 million of stock-based compensation expense. The net cash used in operating activities was approximately $1.83 million for the three months ended March 31, 2020 and consisted primarily of a net loss of approximately $2.25 million and working capital changes of approximately $0.14 million, offset by non-cash expense items of approximately $0.56 million. The approximately $0.14 million of working capital changes was primarily due to an increase in prepaid assets and decreases in accounts payable. Non-cash expense items of approximately $0.56 million primarily consisted of depreciation expense of $0.10 million and stock-based compensation expense of approximately $0.46 million.

Investing Activities

Net cash used in investing activities for the three months ended March 31, 2021 was approximately $0.03 million and consisted of purchases of property and equipment. Net cash used in investing activities for the three months ended March 31, 2020 was approximately $0.05 million and consisted of purchases of property and equipment.

Financing Activities

Net cash provided by financing activities for the three months ended March 31, 2021 was approximately $25.85 million and primarily reflects net proceeds from the sale of shares of our common stock through a follow-on offering. The net cash used by financing activities for the three months ended March 31, 2020 was minimal and primarily reflects payments for finance leases.

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.

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 March 31, 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 March 31, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. — OTHER INFORMATION

ITEM 1. Legal Proceedings

From time to time we may be involved in 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 March 31, 2021, we have used approximately $14.8 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.

ITEM 6. Exhibits

EXHIBIT INDEX

Exhibit No.	Description
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	Purchase Agreement, dated February 23, 2021, between Craig-Hallum Capital Group LLC and Celcuity Inc., incorporated by reference from Exhibit 1.1 to the Company's Current Report on Form 8-K filed with the SEC on February 24, 2021.
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 March 31, 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.

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: May 10, 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)

Exhibit 31.1

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: May 10, 2021

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

Exhibit 31.2

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: May 10, 2021

By /s/ Vicky Hahne
Vicky Hahne
Chief Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the filing of the Quarterly Report on Form 10-Q for the quarter ended March 31, 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: May 10, 2021

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

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the filing of the Quarterly Report on Form 10-Q for the quarter ended March 31, 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: May 10, 2021

By /s/ Vicky Hahne
Vicky Hahne
Chief Financial Officer