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

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 5, 2021

RADIUS HEALTH, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-35726**	**80-0145732**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

22 Boston Wharf Road, 7th Floor, Boston, MA	**02210**
(Address of principal executive offices)	(Zip Code)

(617) 551-4000
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instructions A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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. ☐

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, $0.0001 par value per share	RDUS	The NASDAQ Global Market

Item 2.02 Results of Operations and Financial Condition.

On August 5, 2021, Radius Health, Inc. issued a press release announcing its financial results for the quarter ended June 30, 2021. A copy of the press release is attached hereto as Exhibit 99.1.

The information contained in this Form 8-K (including Exhibit 99.1) is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, except as expressly provided by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Radius Health, Inc. Press Release dated August 5, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 hereunto duly authorized.

RADIUS HEALTH, INC.

Date: August 5, 2021

By: /s/ James G. Chopas
Name: James G. Chopas
Title: Principal Finance and Accounting Officer

Radius Health, Inc.: Second Quarter and Year-to-Date Results

- Repositioned the Company to create meaningful P+L operating leverage
- Dramatic improvement in Adj. EBITDA performance: ($6) million in Q2, 2021 vs. ($29) million in Q2, 2020
- FY 2021 guidance: reiterate Adj. EBITDA of $10 million while reducing TYMLOS revenue from $250 to $240 million
- TYMLOS Q2, 2021 net revenue: $52 million, +3% year-over-year
- TYMLOS new patient growth: Q2, 2021, up 40+% vs. Q2, 2020 and 1H, 2021 up 18% vs. 1H, 2020
- Successful elacestrant BE study: established bioequivalence between clinical and commercial supply

Boston, Mass., August 5, 2021 – Radius Health, Inc. (“Radius” or the “Company”) (Nasdaq: RDUS), today reported its financial results for the second quarter ended June 30, 2021 and year-to-date. In addition, the Company provided an update on components of the business.

“Over the past 12 months we have focused on repositioning the business in a comprehensive manner,” said Kelly Martin, Radius’ President and CEO. Martin continued, “within this effort three specific goals warrant being highlighted. They are, to become a cash flow positive company, to complete enrollment and execute our three ongoing pivotal trials in a high-quality manner, and opportunistically add assets that have the potential to enhance the Company’s value proposition. While there is still more to do, significant progress on all three of these objectives has been made to date.”

Q2 and YTD FINANCIAL HIGHLIGHTS:

- Total Net Revenue vs. prior year:
  - $52 million in Q2, 2021 vs. $50 million in Q2, 2020, +3% year-over-year
  - $108 million 1H, 2021 vs. $98 million 1H, 2020, +10% year-over-year
- TYMLOS Net Revenue:
  - $52 million in Q2, 2021 vs. $50 million in Q2, 2020, +3% year-over-year
  - $97 million 1H, 2021 vs. $98 million 1H, 2020, -1% year-over-year
- Total Company Adjusted EBITDA:
  - ($6) million in Q2, 2021 vs. ($29) million in Q2, 2020
  - ($11) million 1H, 2021 vs. ($55) million 1H, 2020
- FY 2021 guidance: reiterate Adj. EBITDA of $10 million; while reducing TYMLOS revenue from $250 to $240 million
- Liquidity position: $100 million of cash, cash equivalents and marketable securities as of 6/30/2021

ABALOPARATIDE COMMERCIAL UPDATE:

Patient growth continues in both quarter-over-quarter and year-over-year periods. Progress on business and market segment includes:

- TYMLOS year-over-year new patient growth of 40+% in Q2, 2021 and 18% in 1H, 2021
- Top 500 prescribers accounted for ~50% of new patients in Q2, 2021 vs. ~32% in Q1, 2021
- In Q2, 2021, ~50% of our top 125 prescribers were orthopedic or spine-focused practices

- New patient growth attributable to ortho/spine and bone health prescribers accelerated vs. prior quarter

As a reflection of the timing of new patient adds, we are reducing our FY 2021 TYMLOS net revenue guidance by $10 million. Given new patient growth during Q4, 2020 and 1H, 2021, we anticipate that the net revenue for TYMLOS in 2H, 2021 will be stronger than 1H, 2021.

The Company remains focused on making further progress in the commercial market space by concentrating resources, time, and effort on postmenopausal women with osteoporosis at high risk of fracture, including those with recent fractures.

ELACESTRANT UPDATE:

In partnership with the Menarini Group, progress continues to be made on the elacestrant asset and pivotal trial. The topline readout is still expected to occur in 2H, 2021 as previously communicated.

Importantly, there was a successful outcome in the completion of the bioequivalency study (BE study). This critical path item establishes equivalency between the clinical trial product and commercial product and is an important step forward on the progression of the asset.

Life cycle discussions and planning have been held with Menarini, and will continue to take place, regarding the possible therapeutic applications of elacestrant within the selective estrogen degrader (SERD) space.

RAD011 UPDATE:

As announced in a press release on July 23, Radius plans to initiate a seamless Phase 2/3 pivotal trial for patients with Prader-Willi Syndrome (PWS) in Q4, 2021 or early Q1, 2022. This trial will be global and incorporates feedback from the FDA, the KOL community as well as input from patient advocacy organizations.

Second Quarter 2021 Financial Results

Three Months Ended June 30, 2021

Net Loss
For the three months ended June 30, 2021, Radius reported a net loss of $16.8 million, or $0.35 per share, compared to a net loss of $43.9 million, or $0.95 per share, for the three months ended June 30, 2020.

For the three months ended June 30, 2021, non-GAAP adjusted net loss, was $10.5 million, or $0.22 per share, compared to non-GAAP adjusted net loss of $31.1 million, or $0.67 per share, for the three months ended June 30, 2020.

Revenue
For the three months ended June 30, 2021, TYMLOS net product revenues were $51.8 million compared to $50.1 million for the three months ended June 30, 2020.

Costs and Expenses

For the three months ended June 30, 2021, research and development expense was $27.0 million compared to $44.9 million for the three months ended June 30, 2020, a decrease of $17.9 million, or 40%. This decrease was primarily driven by a decrease of $10.6 million in abaloparatide-TD program cost, a $0.4 million decrease in occupancy and depreciation costs, a $4.6 million decrease in compensation expense, which is comprised of a $1.7 million decrease in compensation expense related to headcount and $2.9 million of billed reimbursable expenses, and a $8.8 million decrease in elacestrant program costs, which is comprised of a $6.6 million increase in gross program expenses offset by $15.4 million of billed reimbursable expenses. These decreases were offset by a $0.8 million increase in abaloparatide-SC program costs, a $3.6 million increase in RAD011 program costs, and a $2.1 million increase in professional fees and other expenses.

For the three months ended June 30, 2021, selling, general and administrative expenses were $32.1 million compared to $38.2 million for the three months ended June 30, 2020, a decrease of $6.1 million, or 16%. This decrease was primarily the result of a $2.6 million decrease in compensation cost, a $3.9 million decrease in professional support costs, and a $0.2 million decrease in occupancy and depreciation costs. These decreases were partially offset by a $0.5 million increase in travel and entertainment costs, and a $0.1 million increase in other operating costs.

Six Months Ended June 30, 2021

Net Loss
For the six months ended June 30, 2021, Radius reported a net loss of $32.6 million, or $0.69 per share, compared to a net loss of $81.5 million, or $1.76 per share, for the six months ended June 30, 2020.

For the six months ended June 30, 2021, non-GAAP adjusted net loss, was $19.0 million, or $0.40 per share, compared to non-GAAP adjusted net loss of $58.6 million, or $1.26 per share, for the six months ended June 30, 2020.

Revenue
For the six months ended June 30, 2021, TYMLOS net product revenues were $97.1 million compared to $98.0 million for the six months ended June 30, 2020.

For the six months ended June 30, 2021, license revenue was $11.0 million. No license revenue was recognized for the six months ended June 30, 2020.

Costs and Expenses
For the six months ended June 30, 2021, research and development expense was $58.4 million compared to $83.9 million for the six months ended June 30, 2020, a decrease of $25.5 million, or 30%. This decrease was primarily driven by a decrease of $14.0 million in abaloparatide-TD program cost, a $0.2 million decrease in RAD140 program costs, a $0.8 million decrease in occupancy and depreciation costs, a $9.3 million decrease in compensation expense, which is comprised of a $2.8 million decrease in compensation expense related to headcount and $6.5 million of billed reimbursable expenses, and a $16.4 million decrease in elacestrant program costs, which is comprised of a $9.6 million increase in gross program expenses offset by $26.0 million of billed reimbursable expenses. These decreases were offset by a $6.1 million increase in abaloparatide-SC program costs, a $3.6 million increase in RAD011 program costs, and a $5.8 million increase in professional fees and other expenses.

For the six months ended June 30, 2021, selling, general and administrative expenses were $66.2 million compared to $74.7 million for the six months ended June 30, 2020, a decrease of $8.4 million, or 11%. This

decrease was primarily the result of a $2.0 million decrease in professional support costs, a $6.1 million decrease in compensation cost, and a $0.3 million decrease in other operating costs.

Consolidated Balance Sheets
(Amounts in thousands, except share and per share amounts)

	June 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 99,173	$ 91,436
Restricted cash	567	567
Marketable securities	-	23,280
Accounts receivable, net	23,638	20,310
Inventory	11,310	9,174
Prepaid expenses	11,402	13,279
Other current assets	38,461	22,502
Total current assets	184,551	180,548
Property and equipment, net	702	796
Intangible assets	5,385	5,785
Right of use assets - operating leases	740	3,933
Other assets	1,487	520
Total assets	$ 192,865	$ 191,582
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 14,562	$ 9,925
Accrued expenses and other current liabilities	66,085	59,758
Deferred Revenue	-	1,000
Operating lease liability, current	1,121	2,490
Total current liabilities	81,768	73,173
Convertible notes payable	190,065	213,645
Term loan	147,848	24,905
Operating lease liability, long term	261	3,518
Total liabilities	419,942	315,241
Stockholders’ equity (deficit):		
Common stock, $0.0001 par value; 200,000,000 shares authorized, 47,255,094 shares and 46,779,479 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	5	5
Additional paid-in-capital	1,103,282	1,222,137
Accumulated other comprehensive income (loss)	-	21
Accumulated deficit	(1,330,364)	(1,345,822)
Total stockholders’ equity (deficit)	(227,077)	(123,659)
Total liabilities and stockholders’ equity (deficit)	$ 192,865	$ 191,582

Consolidated Statement of Operations and Comprehensive Loss
(Amounts in thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
REVENUES:				
Product revenue, net	$ 51,797	$ 50,113	$ 97,057	$ 98,037
License Revenue	-	-	11,000	-
Total Revenue	51,797	50,113	108,057	98,037
OPERATING EXPENSES:				
Cost of sales - product	4,394	4,070	8,319	7,931
Cost of sales - intangible amortization	200	200	399	399
Research and development, net of amounts reimbursable (a)	26,950	44,881	58,391	83,890
Selling, general, and administrative	32,143	38,231	66,240	74,664
Income (Loss) from operations	(11,890)	(37,269)	(25,292)	(68,847)
OTHER (EXPENSE) INCOME:				
Other income (expense)	(79)	(68)	(80)	(59)
Interest expense	(4,847)	(6,922)	(9,211)	(13,678)
Interest income	6	379	64	1,050
Gain on extinguishment of debt	-	-	1,960	-
NET LOSS	$ (16,810)	$ (43,880)	$ (32,559)	$ (81,534)
OTHER COMPREHENSIVE LOSS:				
Unrealized gain (loss) from available-for-sale debt securities	-	774	(21)	105
COMPREHENSIVE LOSS	$ (16,810)	$ (43,106)	$ (32,580)	$ (81,429)
LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS - BASIC AND DILUTED:	$ (16,810)	$ (43,880)	$ (32,559)	$ (81,534)
LOSS PER SHARE:				
Basic and diluted	$ (0.35)	$ (0.95)	$ (0.69)	$ (1.76)
WEIGHTED AVERAGE SHARES:				
Basic and diluted	47,391,530	46,420,046	47,114,947	46,345,585

(a) Amounts reimbursable for the three and six months ended June 30, 2021 were $18.5 million and $32.8 million, respectively, and $0 for the three and six months ended June 30, 2020.

Reconciliation of GAAP to Non-GAAP Financial Information
(Unaudited amounts in thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
Net loss reconciliation:				
GAAP net loss	$ (16,810)	$ (43,880)	$ (32,559)	$ (81,534)
Intangible amortization	200	200	399	399
Stock-based compensation expense	5,703	7,840	11,113	13,299
Restructuring charges	-	-	-	-
Depreciation	42	256	94	548
Non-cash interest	413	4,436	771	8,725
Gain on extinguishment of debt	-	-	(1,960)	-
Debt refinancing charges	-	-	3,143	-
Non-GAAP net loss	$ (10,452)	$ (31,148)	$ (18,999)	$ (58,563)
Reconciliation of diluted loss per share:				
GAAP loss per share	$ (0.35)	$ (0.95)	$ (0.69)	$ (1.76)
Intangible amortization	0.01	0.01	0.01	0.01
Stock-based compensation expense	0.11	0.16	0.23	0.29
Restructuring charges	-	-	-	-
Depreciation	-	0.01	-	0.01
Non-cash interest	0.01	0.10	0.02	0.19
Gain on extinguishment of debt	-	-	(0.04)	-
Debt refinancing charges	-	-	0.07	-
Non-GAAP loss per share	$ (0.22)	$ (0.67)	$ (0.40)	$ (1.26)
Reconciliation of shares used in loss per share calculation:				
GAAP shares used in loss per share	47,391,530	46,420,046	47,114,947	46,345,585
Non-GAAP dilutive share adjustments	-	-	-	-
Non-GAAP shares used in loss per share	47,391,530	46,420,046	47,114,947	46,345,585

Webcast and Conference Call

In connection with today's reporting of Second Quarter 2021 Financial Results, Radius will host a conference call and live audio webcast at 8:30 a.m. ET today, August 5, 2021, to review the commercial, research and development, and financial highlights and provide a Company update.

Conference Call Information:
Date: August 5, 2021
Time: 8:30 a.m. ET
Domestic Dial-In Number: 1 (800) 446-1671
International Dial-In Number: 1 (847) 413-3362
Conference ID: 50202646
Webcast Link: https://edge.media-server.com/mmc/p/3bncvtkf

A live audio webcast of the call can be accessed from the Investors section of the Company's website, www.radiuspharm.com. The full text of the announcement and financial results will also be available on the Company's website.

A replay of the conference call will be available on August 5 at 11:30 a.m. ET and the audio webcast of the call will be archived on the Company's website for ninety days. To access the replay, dial (855) 859-2056 or (404) 537-3406 for International, using conference ID number 3659752. The live audio webcast of the call can be accessed from the Investors section of the Company's website, https://ir.radiuspharm.com/events-and-presentations. The full text of the announcement and financial results will also be available on the Company's website.

Use of Non-GAAP Financial Measures
To supplement our condensed consolidated financial statements, which are prepared and presented in accordance with generally accepted accounting principles in the United States (GAAP), we use the following non-GAAP financial measures in this press release: non-GAAP adjusted net loss and non-GAAP net loss per share. These non-GAAP financial measures exclude certain amounts or expenses from the corresponding financial measures determined in accordance with GAAP. Management believes this non-GAAP information is useful for investors, taken in conjunction with Radius' GAAP financial statements, because it provides greater transparency and period-over-period comparability with respect to Radius' operating performance and can enhance investors' ability to identify operating trends in our business. Management uses these measures, among other factors, to assess and analyze operational results and trends and to make financial and operational decisions. Non-GAAP information is not prepared under a comprehensive set of accounting rules and should only be used to supplement an understanding of Radius' operating results as reported under GAAP, not in isolation or as a substitute for, or superior to, financial information prepared and presented in accordance with GAAP. In addition, these non-GAAP financial measures are unlikely to be comparable with non-GAAP information provided by other companies. The determination of the amounts that are excluded from non-GAAP financial measures is a matter of management judgment and depends upon, among other factors, the nature of the underlying expense or income amounts. Reconciliations between these non-GAAP financial measures and the most comparable GAAP financial measures for the three months ended June 30, 2021 and 2020 are included in the tables accompanying this press release after the unaudited condensed consolidated financial statements.

About Radius
Radius is a commercial biopharmaceutical company committed to serving patients with unmet medical needs in endocrinology and other therapeutic areas. Radius' lead product, TYMLOS® (abaloparatide) injection, was

approved by the U.S. Food and Drug Administration for the treatment of postmenopausal women with osteoporosis at high risk for fracture. The Radius clinical pipeline includes investigational abaloparatide injection for potential use in the treatment of men with osteoporosis; an investigational abaloparatide transdermal system for potential use in the treatment of postmenopausal women with osteoporosis; the investigational drug, elacestrant (RAD1901), for potential use in the treatment of hormone-receptor positive breast cancer out-licensed to Menarini Group; and the investigational drug RAD011, a synthetic cannabidiol oral solution with potential utilization in multiple endocrine and metabolic orphan diseases, initially targeting Prader-Willi Syndrome.

About TYMLOS (abaloparatide) injection
TYMLOS (abaloparatide) injection was approved by the U.S. Food and Drug Administration for the treatment of postmenopausal women with osteoporosis at high risk for fracture defined as history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.

About ATOM Phase 3 Study
The ATOM Phase 3 study is a randomized, double-blind, placebo-controlled study to assess efficacy and safety of abaloparatide injection in 228 men with osteoporosis. The primary endpoint is change in lumbar spine BMD at 12 months compared with placebo, and if successful, will form the basis of a supplemental NDA seeking to expand the use of TYMLOS to treat men with osteoporosis at high risk for fracture.

About the Abaloparatide Transdermal System and wearABLe Phase 3 Study
The abaloparatide transdermal system was developed in a collaboration between Radius and Kindeva Drug Delivery (“Kindeva”) (formerly 3M Drug Delivery Systems) with the application of Kindeva’s innovative microstructured transdermal system technology. The wearABLe study is a pivotal, randomized, open label, active-controlled, bone mineral density (“BMD”) non-inferiority bridging study that will evaluate the efficacy and safety of abaloparatide transdermal system versus TYMLOS (abaloparatide) injection in approximately 500 patients with postmenopausal osteoporosis at high risk for fracture. The primary endpoint of the study is the percentage change in lumbar spine BMD at 12 months.

About Elacestrant (RAD1901) and EMERALD Phase 3 Study
Elacestrant is a selective estrogen receptor degrader (SERD), out-licensed to Menarini Group, which is being evaluated for potential use as a once daily oral treatment in patients with ER+/ HER2- advanced breast cancer. Studies completed to date indicate that the compound has the potential for use as a single agent or in combination with other therapies for the treatment of breast cancer. The EMERALD Phase 3 trial is a randomized, open label, active-controlled study evaluating elacestrant as second- or third-line monotherapy in ER+/HER2- advanced/metastatic breast cancer patients. The study has enrolled 466 patients who have received prior treatment with one or two lines of endocrine therapy, including a cyclin-dependent kinase (CDK) 4/6 inhibitor. Patients in the study were randomized to receive either elacestrant or the investigator’s choice of an approved hormonal agent. The primary endpoint of the study is progression-free survival (PFS) in the overall patient population and in patients with estrogen receptor 1 gene (ESR1) mutations. Secondary endpoints include evaluation of overall survival (OS), objective response rate (ORR), and duration of response (DOR).

About Prader-Willi Syndrome
PWS, an orphan disease, is a complex genetic disorder with clinical manifestations on the endocrine and neurological systems. Clinical signs of PWS develop throughout childhood, with hyperphagia and anxiety ranked as the key clinical features seeking medical attention by caregivers of individuals with PWS. Hyperphagia is a relentless, insatiable, pathological drive to eat that requires caregivers to strictly manage access to food through

the locking of cabinets and refrigerators. PWS is recognized as the leading genetic cause of life-threatening obesity in children. As life-threatening hyperphagia persists into adulthood, metabolic syndrome expressed through obesity and diabetes can develop and contribute to morbidity and mortality. In addition to food-related behaviors, the behavioral symptoms commonly observed in PWS include high irritability, habitual skin picking, oppositional defiance and cognitive rigidity. There are currently no approved therapies to treat this disorder's hyperphagia, irritability, or metabolic aspects. In the U.S., PWS occurs in approximately one out of every 15,000 births.

About RAD011
Investigational drug RAD011 is a pharmaceutical-grade synthetic cannabidiol oral solution, manufactured utilizing traditional pharmaceutical manufacturing processes. The product has purity specifications that meet standardized regulatory and quality control requirements and, compared to the process of developing a plant-derived product, the synthetic manufacturing process usually enables increased consistency and greater precision in the product supply. RAD011 has been assessed in over 150 patients across multiple indications and has potential utilization in multiple diseases. Radius is initially targeting Prader-Willi Syndrome (PWS) and anticipates initiating a seamless pivotal Phase 2/3 study for patients with PWS in the fourth quarter of 2021 or first quarter of 2022.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation statements regarding our expectations with respect to the continued commercialization of TYMLOS in the U.S.; our clinical trials, studies and other regulatory initiatives, including the EMERALD Phase 3 clinical trial of elacestrant and our planned seamless Phase 2/3 trial for RAD011; and our goals for the development of our product candidates.

These forward-looking statements are based on management's current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: the adverse impact the ongoing COVID-19 pandemic is having and is expected to continue to have on our business, financial condition and results of operations, including our commercial operations and sales, clinical trials, preclinical studies, and employees; quarterly fluctuation in our financial results; our dependence on the success of TYMLOS, and our inability to ensure that TYMLOS will obtain regulatory approval outside the U.S. or be successfully commercialized in any market in which it is approved, including as a result of risk related to coverage, pricing and reimbursement; risks related to competitive products; risks related to our ability to successfully enter into collaboration, partnership, license or similar agreements; risks related to clinical trials, including our reliance on third parties to conduct key portions of our clinical trials and uncertainty that the results of those trials will support our product candidate claims; the risk that adverse side effects will be identified during the development of our product candidates or during commercialization, if approved; risks related to manufacturing, supply and distribution; and the risk of litigation or other challenges regarding our intellectual property rights. These and other important risks and uncertainties discussed in our filings with the Securities and Exchange Commission, or SEC, including under the caption "Risk Factors" in our Annual Report on Form 10-K for the year ending December 31, 2020 and subsequent filings with the SEC, could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management's estimates as of the date of this press release. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change. These

forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

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