

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): May 7, 2020

**RADIUS HEALTH, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation)

**001-35726**

(Commission File Number)

**80-0145732**

(IRS Employer Identification No.)

**950 Winter Street, Waltham, MA**

(Address of principal executive offices)

**02451**

(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))

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

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.

**Item 2.02 Results of Operations and Financial Condition.**

On May 7, 2020, Radius Health, Inc. issued a press release announcing its financial results for the quarter ended March 31, 2020. 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Radius Health, Inc. Press Release dated May 7, 2020</a>
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: May 7, 2020

By: /s/ Jon Mahlowitz  
Name: Jon Mahlowitz  
Title: General Counsel



## Radius Health Announces First Quarter 2020 Operating Results

*TYMLOS® U.S. net sales of \$48 million, with 61% year over year growth*

*Our three Phase 3 studies continue to advance amid slowdown in recruitment due to COVID-19 pandemic. Anticipated data read-outs remain on track for second half of 2021.*

*Due to anticipated impact of pandemic, 2020 TYMLOS U.S. net revenue guidance mid-point reduced by 10% to between \$190M and \$220M. Full year cash burn is expected to be below \$100M.*

*Kelly Martin appointed President and Chief Executive Officer as of April 28 after Jesper Hoeiland resigned to return to Denmark.*

*Conference call scheduled for 4:45 p.m. ET today*

WALTHAM, Mass., May 7, 2020 -- Radius Health, Inc. ("Radius" or the "Company") (Nasdaq: RDUS), today reported its financial and operating results for the first quarter ended March 31, 2020 and provided a business update.

"In these challenging and unprecedented times, I am proud of the Radius team's quick response and key measures to ensure the safety of our employees, while also providing patients and customers with uninterrupted access to TYMLOS and our investigational medicines," said Jesper Hoeiland, former Chief Executive Officer of Radius. "I am very enthusiastic about the prospects for Radius and look forward to working with Kelly to make this transition as seamless and effective as possible," added Jesper.

"I look forward to building on the strong momentum established by Jesper with the TYMLOS franchise and guiding the development of the Company and the achievement of its objectives and advancing it to the next level," said Kelly Martin, President and CEO of Radius Health.

### **COVID-19 Response**

In response to the ongoing COVID-19 pandemic, Radius has implemented a number of initiatives to support the safety of its employees and customers and mitigate impacts on the supply of TYMLOS and its investigational medicines to patients and healthcare providers, and advance its clinical studies. Our current expectations for the timing of enrollment and completion of our ongoing clinical trials, particularly for wearABLE and EMERALD, are based on our assumptions that during the second half of 2020, the effects of the COVID-19 pandemic will begin to subside as "shelter-in-place" policies and other restrictive measures are relaxed. As a result, we believe that enrollment rates will increase to near normal pre-pandemic levels, and for our wearABLE trial, our ex-U.S. trial sites are activated within the timelines we expect. The Company will continue to assess the pandemic and any potential impact it may

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have on its operations, financial condition, guidance and plans. The mitigation measures that we have implemented to address potential challenges from the pandemic include the following:

- **Safety of Employees:** A work-from-home mandate for employees was implemented in mid-March with enhanced utilization of technical tools and capabilities to accomplish secure remote access and conduct of virtual business.
- **Patient Access to TYMLOS:** With the implementation of a new streamlined distribution model utilizing several specialty distributors, Radius is able to support seamless patient access to TYMLOS. TYMLOS is administered at home and over 90% of patients currently have the option to receive TYMLOS via home delivery. To date, Radius has observed no disruptions in its supply chain for the production and shipments of TYMLOS or its clinical trial medications. The Company has secured inventories of TYMLOS and its investigational medications until the end of the year and continues to manufacture to ensure continuity of supply.
- **Continued Patient Care and HCP Support:** Radius' commercial organization is providing virtual interactions to connect with healthcare providers, assisting their offices with continued access to TYMLOS tools and enabling supply of samples via online processes. The Company's clinical educator team has also switched to virtual practices to continue support to both new patients and patients on treatment.
- **Supporting Ongoing Clinical Trials:** Radius is working with clinical trial sites and clinical research organizations to provide virtual capabilities for site initiations, remote trial monitoring, virtual safety assessments at home, options for local procedures to reduce travel, and home delivery of investigational products. The Company is following regulatory guidance from the FDA and EMA on the conduct of clinical trials during the COVID-19 pandemic, providing support to each site, and prioritizing study visits for key efficacy assessments to maintain data quality and integrity.

#### **TYMLOS (abaloparatide) injection**

- First quarter 2020 U.S. net sales of TYMLOS were \$47.9 million, a 61% increase over the first quarter of 2019.
- By the end of the first quarter 2020, TYMLOS' average U.S. anabolic market share rose to 44% and it achieved a 53% share of new anabolic patient starts. With this growth trajectory, Radius remains confident TYMLOS will become the U.S. anabolic market leader in 2020 (based on TRx<sup>1</sup>).

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<sup>1</sup> Total Market Share, TRx PMOT. Source: IQVIA

- In April, there has been a decline in new patient starts due to the decrease in physician office visits resulting from government restrictions in response to the pandemic. Assuming that during the second half of the year the impacts of the pandemic begin to subside as the shelter-in-place measures are relaxed and states re-open, Radius expects new TYMLOS prescriptions to increase and return to near normal pre-pandemic levels.
- During the first quarter of 2020, Radius executed a transition of the Company's external distribution model from full-line wholesalers to specialty distributors and specialty pharmacies. Under this distribution model, both the specialty distributors and specialty pharmacies take physical delivery of TYMLOS and pharmacies dispense TYMLOS directly to patients. This new streamlined distribution model has further improved the home delivery process for TYMLOS, achieved sustainable cost efficiencies, and is expected to have a positive impact on the gross to net sales ratio for TYMLOS.

### **Pipeline Highlights**

#### **Abaloparatide-SC**

- The ATOM Phase 3 Study, which is assessing the efficacy and safety of abaloparatide-SC in men with osteoporosis, has completed approximately 90% of its enrollment. Radius expects to complete recruitment this year and report top-line data in the second half of 2021.
- The TYMLOS bone histomorphometry study, which evaluated the early effects of abaloparatide-SC on tissue-based indices of bone formation and resorption in postmenopausal women, met its primary endpoint of change from baseline to 3 months in mineralizing surface in the cancellous bone envelope, which is a strong indicator of bone formation. Radius expects to present data from this study in the second half of 2020.

#### **Abaloparatide-Patch**

- The wearABLE Phase 3 study continues to advance enrollment amid slowdown from the pandemic. The screening failure rate has significantly decreased after the implementation of a revised enrollment plan and addition of targeted bone specialty sites in the U.S. In Europe, regulatory reviews are underway, with first conditional approvals already received for sites to be initiated in the second quarter of this year.
- At this time, Radius expects to complete recruitment in the later part of the third quarter of 2020 and report top-line data from the study in the second half of 2021.

## **Elacestrant**

- The EMERALD Phase 3 study is continuing to advance its global enrollment. The recruitment activity which slowed down in April because of the pandemic is resuming at sites in countries where COVID-19 restrictions have been eased.
- At this time, Radius expects completion of recruitment in the study in the fourth quarter of this year and to report top-line data in the second half of 2021.

## **Financial Highlights and Guidance**

- Radius has decreased its full-year TYMLOS U.S. net revenue guidance mid-point by 10%, taking the impacts from the COVID-19 pandemic into consideration, and assuming a return to normalized pre-pandemic demand patterns in the second half of 2020. At this time, the Company expects full-year TYMLOS U.S. net revenue to be between \$190 and \$220 million and its full-year cash burn to be below \$100 million, excluding net cash from the existing non-dilutive credit facility.
- Radius had \$23 million net cash outflows in the first quarter and closed the quarter with a \$138 million cash balance. The Company has drawn \$10M from the term loan that it secured in January. Radius expects access to non-dilutive financing for another \$30M from the second and third tranche of the term loan and up to \$20M from the working capital revolver that it entered into in January.

## **Anticipated Milestones in 2020**

- Clinical Pipeline
  - Complete recruitment in Phase 3 ATOM study
  - Complete recruitment in Phase 3 wearABLE study
  - Complete recruitment in Phase 3 EMERALD study
- TYMLOS
  - Grow full-year TYMLOS U.S. net sales to between \$190 and \$220 million
  - Capture U.S. anabolic TRx market leadership in 2H 2020

## **First Quarter 2020 Financial Results**

### **Three Months Ended March 31, 2020**

For the three months ended March 31, 2020, Radius reported a net loss of \$37.7 million, or \$0.81 per share, compared to a net loss of \$42.8 million, or \$0.94 per share, for the three months ended March 31, 2019.

For the three months ended March 31, 2020, non-GAAP adjusted net loss, which excludes expenses related to stock-based compensation, depreciation, non-cash interest obligations under debt obligations, and amortization of intangible assets, was \$27.4 million, or \$0.59 per share, compared to non-GAAP adjusted net loss of \$31.8 million, or \$0.70 per share, for the three months ended March 31, 2019.

For the three months ended March 31, 2020, we recorded approximately \$47.9 million of net product revenue compared to \$29.8 million for the three months ended March 31, 2019.

For the three months ended March 31, 2020, research and development expense was \$39.0 million compared to \$23.3 million for the three months ended March 31, 2019, an increase of \$15.8 million, or 68%. This increase was primarily driven by a \$11.1 million increase in abaloparatide-patch program costs, a \$3.4 million increase in elacestrant program costs, a \$0.9 million increase in professional support costs, and a \$0.4 million increase in abaloparatide-SC program costs.

For the three months ended March 31, 2020, selling, general and administrative expense was \$36.4 million compared to \$41.2 million for the three months ended March 31, 2019, a decrease of \$4.8 million, or 12%. This decrease was primarily the result of a \$2.9 million decrease in professional support costs, a \$1.4 million decrease in compensation and travel entertainment costs, and a \$0.6 million decrease in occupancy and depreciation costs. These decreases were partially offset by a \$0.1 million increase in other operating expenses.

As of March 31, 2020, Radius had \$138.5 million in cash, cash equivalents, restricted cash, and marketable securities. Based upon our cash, cash equivalents and marketable securities balance as of March 31, 2020 and funds available to us through our credit facilities, we believe that, prior to the consideration of potential proceeds from partnering and/or collaboration activities, we have sufficient capital to fund our development plans, U.S. commercial and other operational activities for at least twelve months from the date of this press release.

## Consolidated Balance Sheets

(Amounts in thousands, except share and per share amounts)

	<u>March 31,</u> <u>2020</u>	<u>December 31,</u> <u>2019</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 40,723	\$ 69,886
Restricted cash	567	567
Marketable securities	97,257	91,015
Accounts receivable, net	30,371	23,289
Inventory	6,002	5,323
Prepaid expenses	9,244	12,131
Other current assets	1,214	846
Total current assets	<u>185,378</u>	<u>203,057</u>
Property and equipment, net	2,000	2,293
Intangible assets	6,384	6,583
Right of use assets - operating leases	7,304	6,704
Other assets	514	514
Total assets	<u>\$ 201,580</u>	<u>\$ 219,151</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>		
Current liabilities:		
Accounts payable	\$ 9,192	\$ 6,030
Accrued expenses and other current liabilities	49,411	53,030
Operating lease liability, current	2,138	2,198
Total current liabilities	<u>60,741</u>	<u>61,258</u>
Convertible notes payable	199,880	195,591
Term loan	9,939	-
Operating lease liability, long term	5,173	4,581
Total liabilities	<u>275,733</u>	<u>261,430</u>
Stockholders' equity (deficit):		
Common stock, \$0.0001 par value; 200,000,000 shares authorized, 46,387,437 shares and 46,189,870 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively	5	5
Additional paid-in-capital	1,200,776	1,194,327
Accumulated other comprehensive income (loss)	(666)	3
Accumulated deficit	<u>(1,274,268)</u>	<u>(1,236,614)</u>
Total stockholders' equity (deficit)	<u>(74,153)</u>	<u>(42,279)</u>
Total liabilities and stockholders' equity (deficit)	<u>\$ 201,580</u>	<u>\$ 219,151</u>

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

	Three Months Ended March 31,	
	2020	2019
<b>REVENUES:</b>		
Product revenue, net	\$ 47,923	\$ 29,844
<b>OPERATING EXPENSES:</b>		
Cost of sales - product	3,861	3,030
Cost of sales - intangible amortization	200	200
Research and development	39,009	23,259
Selling, general, and administrative	36,433	41,186
Loss from operations	(31,580)	(37,831)
<b>OTHER (EXPENSE) INCOME:</b>		
Other income (expense)	11	4
Interest expense	(6,756)	(6,037)
Interest income	671	1,104
<b>NET LOSS</b>	<b>\$ (37,654)</b>	<b>\$ (42,760)</b>
<b>OTHER COMPREHENSIVE LOSS:</b>		
Unrealized gain (loss) from available-for-sale debt securities	(669)	474
<b>COMPREHENSIVE LOSS</b>	<b>\$ (38,323)</b>	<b>\$ (42,286)</b>
<b>LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS - BASIC AND DILUTED:</b>	<b>\$ (37,654)</b>	<b>\$ (42,760)</b>
<b>LOSS PER SHARE:</b>		
Basic and diluted	\$ (0.81)	\$ (0.94)
<b>WEIGHTED AVERAGE SHARES:</b>		
Basic and diluted	46,271,123	45,671,502

**Reconciliation of GAAP to Non-GAAP Financial Information**

(Unaudited amounts in thousands, except share and per share amounts)

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<u>2020</u>	<u>2019</u>
<b>Net loss reconciliation:</b>		
GAAP net loss	\$ (37,654)	\$ (42,760)
Intangible amortization	200	200
Stock-based compensation expense	5,459	6,115
Restructuring charges	-	147
Depreciation	292	433
Non-cash interest	4,289	3,750
Operating Lease Impairment	-	339
Non-GAAP net loss	<u>\$ (27,414)</u>	<u>\$ (31,776)</u>
<b>Reconciliation of diluted loss per share:</b>		
GAAP loss per share	\$ (0.81)	\$ (0.94)
Intangible amortization	-	-
Stock-based compensation expense	0.12	0.14
Restructuring charges	-	-
Depreciation	0.01	0.01
Non-cash interest	0.09	0.08
Operating Lease Impairment	-	0.01
Non-GAAP loss per share	<u>\$ (0.59)</u>	<u>\$ (0.70)</u>
<b>Reconciliation of shares used in loss per share calculation:</b>		
GAAP shares used in loss per share	46,271,123	45,671,502
Non-GAAP dilutive share adjustments	-	-
Non-GAAP shares used in loss per share	<u>46,271,123</u>	<u>45,671,502</u>

## **Webcast and Conference Call**

In connection with today's reporting of First Quarter 2020 Financial Results, Radius will host a conference call and live audio webcast at 4:45 p.m. ET today, May 7, 2020, to review the commercial, research and development, and financial highlights and provide a Company update.

### **Conference Call Information:**

**Date:** May 7, 2020

**Time:** 4:45 p.m. ET

**Domestic Dial-in Number:** (866) 323-7965

**International Dial-in Number:** (346) 406-0961

**Conference ID:** 5683238

**Live webcast:** <https://edge.media-server.com/mmc/p/hstkyn2t>

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

For those unable to participate in the conference call or webcast, a replay will be available on Thursday, May 7, 2020 at 7:45 p.m. ET and will be archived on the Company's website for 90 days. To access the replay, dial (855) 859-2056 for U.S. or (404) 537-3406 for International, using conference ID number 5683238

### **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 March 31, 2019 and 2020 are included in the tables accompanying this press release after the unaudited condensed consolidated financial statements.

### **About Radius**

Radius is a science-driven fully integrated biopharmaceutical company that is committed to developing and commercializing innovative endocrine therapeutics. 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 the investigational use of abaloparatide injection for the treatment of men with osteoporosis; an investigational abaloparatide-patch for potential use in osteoporosis; the investigational drug elacestrant (RAD1901) for potential use in hormone-receptor positive breast cancer; and the investigational drug RAD140, a non-steroidal, selective androgen receptor modulator (SARM) under investigation for potential use in hormone-receptor positive breast cancer. For more information, please visit [www.radiuspharm.com](http://www.radiuspharm.com).

### **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-SC in approximately 225 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 Abaloparatide-Patch and wearABLE Phase 3 Study**

Abaloparatide-patch was developed in a collaboration between Radius and 3M Company with the application of 3M's innovative microstructured transdermal patch technology. The Phase 3 wearABLE abaloparatide-patch study is the first pivotal study to evaluate treatment using a novel non-injectable delivery of an anabolic therapy. The wearABLE Phase 3 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-patch versus TYMLOS (abaloparatide injection) in approximately 470 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)**

Elacestrant is a selective estrogen receptor degrader (SERD), which is being evaluated for potential use as a once daily oral treatment for hormone-receptor positive breast cancer. Elacestrant is currently being investigated for potential use in patients with advanced estrogen receptor positive, HER2 negative, breast cancer, the most common form of the disease. 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.

## 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 the impact of COVID-19 on our business and results of operations, including our assumption that during the second half of 2020, certain impacts on our business from the COVID-19 pandemic will begin to subside; our expectations for full-year TYMLOS U.S. net sales and our full-year cash burn; our expectations regarding commercialization of TYMLOS in the U.S., including expectations that it will become the leader in the U.S. anabolic osteoporosis market and the timing thereof; our expectations regarding cost efficiencies resulting from the change in our distribution model for TYMLOS, including expectations that it will have a positive impact on the gross to net sales ratio for TYMLOS; our expectations regarding our regulatory submissions, including the timing thereof; our expectations regarding our clinical trials, including the design and timing thereof and our expected timing for completing enrollment and reporting top-line data in each of our Phase 3 clinical trials; the progress in the development of our product candidates, including abaloparatide-patch, elacestrant (RAD1901) and RAD140; each of the statements under the headings “Anticipated Milestones in 2020”; the sufficiency of our cash, cash equivalents, restricted cash, and marketable securities balance; and the potential clinical uses and therapeutic and other benefits of our product candidates, including abaloparatide-patch, elacestrant and RAD140.

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; we may need to raise additional funding, which may not be available; risks related to raising additional capital, including as a result of the COVID-19 pandemic; our limited operating history; 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 or partnership agreements and any executed collaboration or partnership agreements failing to be successful; risks related to clinical trials, including our reliance on third parties to conduct key portions of our clinical trials and uncertainty that results 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, 2019 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.

**Investor & Media Relations Contact:**

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