
**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 7, 2018

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)

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

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.

Item 2.02 Results of Operations and Financial Condition.

On August 7, 2018, Radius Health, Inc. issued a press release announcing its financial results for the quarter ended June 30, 2018. 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	Radius Health, Inc. Press Release dated August 7, 2018

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 7, 2018

By: /s/ Jose Carmona

Name: Jose Carmona

Title: Chief Financial Officer



Radius Health Reports Second Quarter 2018 Financial and Operating Results and Provides Business Update

Second quarter 2018 TYMLOS sales increase to \$22.6 million, a 56% increase over the first quarter of 2018

TYMLOS' share in the U.S. anabolic osteoporosis market increased to an average of 19% in the second quarter from 13% in the prior quarter

Radius maintains its 19-21% average 2018 U.S. anabolic osteoporosis market share guidance for TYMLOS and increases its expectations for the U.S. anabolic market to grow by 7-9% in volume versus 2017

Conference call scheduled for 8:00 a.m. ET today

WALTHAM, Mass., August 7, 2018 -- Radius Health, Inc. ("Radius" or the "Company") (Nasdaq: RDUS), today reported its financial results for the second quarter ended June 30, 2018 and provided a business update.

"We are very pleased to report our continued progress in increasing the U.S. anabolic osteoporosis market share for TYMLOS and remain on track to meet our market share guidance for the year. We are also excited to see continued growth in the U.S. anabolic market since the launch of TYMLOS. Bone building anabolic therapies can offer significant benefits to high risk osteoporosis patients and are increasingly recommended by KOLs for use in this large and under-served patient population," said Jesper Hoeiland, President and Chief Executive Officer of Radius.

"We are on track to deliver on our key milestones and advance our clinical pipeline forward," Mr. Hoeiland concluded.

TYMLOS® (abaloparatide) injection

- Second quarter 2018 sales of TYMLOS in the U.S. were \$22.6 million, an increase of 56% from the first quarter of 2018. TYMLOS prescriptions accounted for on average 19% of the total U.S. anabolic osteoporosis market (based on Patient Months on Therapy, TRx PMOT) and reached 34% of new anabolic patient starts (based on New Patients to Brand, NBRx PMOT).
 - TYMLOS U.S. market access increased to approximately 265 million covered lives. This represents 95% coverage in Commercial and Medicaid/All Other; and 44% coverage in Medicare Part D for a total of 88% of the U.S. insured population. In Commercial, the access has led to a monthly growth in total prescriptions of 257% in June 2018 compared to December 2017.
 - In June 2018, the U.S. Food and Drug Administration (FDA) approved a labeling supplement for TYMLOS to revise the needle length in the Instructions for Use from 8 mm to 5 to 8 mm. The Company believes health care providers, specialty pharmacies, and patients may prefer a shorter needle size for injectable products like TYMLOS.
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- Radius maintains its guidance for TYMLOS to capture on average 19-21% of the U.S. anabolic osteoporosis market in 2018. Based on the continued growth trajectory of the anabolic market since TYMLOS launched in May 2017, Radius now expects the U.S. anabolic market to grow at 7-9% in volume versus 2017.

Pipeline Highlights

Abaloparatide-Transdermal Patch (abaloparatide-patch)

- At its Osteoporosis Investor Day event on June 8th, Radius presented further analyses of clinical and modelling data from its abaloparatide-patch program that support the Company's Phase 3 trial's primary objective of achieving BMD (bone mineral density) non-inferiority to abaloparatide-SC. Radius is on track with its preparation for the Phase 3 trial and expects to start the study in mid-2019.

Abaloparatide - Subcutaneous (SC)

- **Publication of ACTIVEExtend Phase 3 data**
In May 2018, results from the ACTIVEExtend Study were published in The Journal of Clinical Endocrinology & Metabolism (JCEM). The significant reduction in the incidence of fractures seen from treatment with TYMLOS for 18 months in the ACTIVE Phase 3 Study was maintained in patients who received follow-up alendronate therapy for two years. At the 43-month timepoint, the previous TYMLOS-treated patients had a significant 84 percent relative risk reduction ($p < 0.0001$) in vertebral fractures and a 39% risk reduction in nonvertebral fractures ($p = 0.038$). The Company submitted a labeling supplement to the FDA in connection with the ACTIVEExtend results in December 2017.
- **Histomorphometry Study**
In July 2018, Radius initiated a bone histomorphometry study, which will enroll approximately 25 postmenopausal women with osteoporosis to evaluate the early effects of TYMLOS on tissue-based bone remodeling and structural indices. The study is designed to help understand and differentiate early effects of TYMLOS on bone formation and structure.
- **CHMP Opinion**
In July 2018, Radius announced that, following a re-examination procedure, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency had communicated a negative trend vote for the Company's MAA for abaloparatide-SC for the treatment of osteoporosis in postmenopausal women at increased risk for fracture. On July 27, 2018, the CHMP communicated that it maintained its negative opinion on the MAA at its formal final vote. Radius will continue its efforts to make abaloparatide-SC available outside the U.S., via its collaboration with Teijin Limited in Japan and in other markets through partnership agreements.

Elacestrant (RAD1901)

- Based on EMA and FDA feedback, Radius currently intends to conduct a single, randomized, comparator controlled Phase 3 trial of elacestrant as a third-line monotherapy in approximately 300 patients with ER positive/HER2 negative advanced/metastatic breast cancer. Depending on the results, this study is expected to support applications for global marketing approvals for elacestrant. Patients in the study would be randomized to receive either elacestrant or an investigator's choice of an approved hormonal agent and the primary endpoint of the study will be progression-free survival (PFS). Start-up activities for the randomized study are well underway and Radius will provide further study details when the Phase 3 trial is initiated, which the Company expects will be in the second half of 2018.

RAD140

- Patient enrollment is ongoing in the Phase 1 study evaluating the safety and maximum tolerated dose of RAD140, a nonsteroidal selective androgen receptor modulator (SARM), in patients with hormone receptor-positive, locally advanced or metastatic breast cancer. The Company expects to provide an update on the RAD140 development program by the end of 2018.

Anticipated Upcoming Milestones

- Elacestrant
 - Initiate a Phase 3 clinical trial as third-line monotherapy in advanced/metastatic ER-positive/HER2-negative breast cancer patients in the second half of 2018.
 - Collaboration agreement for elacestrant combination therapy
- RAD140
 - Continue enrollment in the Phase 1 study and provide a program update by the end of 2018
- Abaloparatide
 - Enter into a partnership for the potential commercialization of abaloparatide-SC outside the U.S. and Japan

Expected Radius Presentations at Upcoming Conferences in Q3 2018

- On September 12-14, the Company will present and host one-on-one meetings at the Morgan Stanley 16th Annual Global Healthcare Conference in New York, NY.

Second Quarter 2018 Financial Results

Three Months Ended June 30, 2018

For the three months ended June 30, 2018, Radius reported a net loss of \$68.9 million, or \$1.52 per share, compared to a net loss of \$68.4 million, or \$1.58 per share, for the three months ended June 30, 2017.

For the three months ended June 30, 2018, non-GAAP adjusted net loss, which excludes expenses related to stock-based compensation, restructuring plans, non-cash interest obligations under debt obligations, litigation related payments, and amortization of intangible assets, was \$45.1 million, or \$0.99 per share, compared to non-GAAP adjusted net loss of \$57.0 million, or \$1.31 per share, for the three months ended June 30, 2017.

For the three months ended June 30, 2018, TYMLOS net product revenues were \$22.6 million compared to approximately \$1.0 million for the three months ended June 30, 2017.

Radius made a \$10.8 million payment to Ipsen in the second quarter pursuant to a final decision in arbitration proceedings with Ipsen, which is reflected in other operating expenses.

Research and development expense for the three months ended June 30, 2018, was \$26.3 million compared to \$19.7 million for the three months ended June 30, 2017, an increase of \$6.7 million, or 34%. This increase was primarily driven by a \$4.2 million increase in elacestrant project costs, a \$1.4 million increase in abaloparatide-patch project costs, a \$1.0 million increase in RAD140 project costs, a \$0.4 million increase in abaloparatide-SC project costs, a \$0.4 million increase in other project related expenses, and restructuring charges of \$0.8 million related to the closure of the Company's New Jersey office. These increases were partially offset by a \$0.9 million decrease in personnel related spending.

For the three months ended June 30, 2018, selling, general and administrative expense was \$48.6 million compared to \$50.1 million for the three months ended June 30, 2017, a decrease of \$1.5 million, or 3%. This decrease was primarily the result of decreases of \$1.2 million and \$0.8 million in compensation and travel related expenses. These decreases were partially offset by restructuring charges of \$0.6 million related to the re-allocation of commercial resources.

Six Months Ended June 30, 2018

For the six months ended June 30, 2018, Radius reported a net loss of \$130.4 million, or \$2.89 per share, compared to a net loss of \$125.4 million, or \$2.90 per share, for the six months ended June 30, 2017.

For the six months ended June 30, 2018, non-GAAP adjusted net loss, which excludes expenses related to stock-based compensation, restructuring plans, non-cash interest obligations under debt obligations, litigation related payments, and amortization of intangible assets, was \$95.6 million, or \$2.12 per share, compared to non-GAAP adjusted net loss of \$104.8 million, or \$2.42 per share, for the six months ended June 30, 2017.

For the six months ended June 30, 2018, TYMLOS net product revenues were \$37.2 million compared to approximately \$1.0 million for the six months ended June 30, 2017.

Research and development expense for the six months ended June 30, 2018, was \$49.2 million compared to \$39.2 million for the six months ended June 30, 2017, an increase of \$10.0 million, or 26%. This increase was primarily driven by a \$4.8 million increase in elacestrant project costs, a \$2.9 million increase in abaloparatide-SC project costs, a \$1.5 million increase in abaloparatide-patch project costs, a \$1.3 million increase in RAD140 project costs, and restructuring charges of \$0.8 million related to the closure of the Company's New Jersey office. These increases were partially offset by a \$0.5 million decrease in other project related expenses.

Selling, general, and administrative expense for the six months ended June 30, 2018, was \$96.6 million compared to \$88.2 million for the six months ended June 30, 2017, an increase of \$8.4 million, or 10%. This increase was primarily the result of increases of \$5.4 million and \$1.8 million in compensation and travel related expenses, respectively. These increases were partially offset by restructuring charges of \$0.6 million related to the re-allocation of commercial resources.

As of June 30, 2018, Radius had \$318.5 million in cash, cash equivalents, restricted cash, marketable securities and investments. Based upon our cash, cash equivalents, marketable securities and investments balance as of June 30, 2018, we believe that, prior to the consideration of proceeds from partnering and/or collaboration activities, we have sufficient capital to fund our development plans, U.S. commercial and other operational activities for not less than twelve months from the date of this press release.

Condensed Consolidated Balance Sheets

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

	<u>June 30,</u> <u>2018</u>	<u>December 31,</u> <u>2017</u>
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 51,441	\$ 118,564
Restricted cash	555	55
Marketable securities	179,730	134,714
Accounts receivables, net	10,957	4,441
Inventory	6,220	4,366
Prepaid expenses	6,527	5,175
Other current assets	1,467	2,191
Total current assets	<u>256,897</u>	<u>269,506</u>
Investments	86,763	176,978
Property and equipment, net	5,210	6,195
Intangible assets	7,781	8,180
Other assets	633	799
Total assets	<u>\$ 357,284</u>	<u>\$ 461,658</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 2,532	\$ 3,915
Accrued expenses and other current liabilities	45,177	49,512
Total current liabilities	<u>47,709</u>	<u>53,427</u>
Other non-current liabilities	142	189
Note payable	172,674	166,006
Total liabilities	<u>220,525</u>	<u>219,622</u>
Stockholders' equity:		
Common stock, \$.0001 par value; 200,000,000 shares authorized, 45,476,455 shares and 44,616,586 shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively	5	4
Additional paid-in-capital	1,150,765	1,124,630
Accumulated other comprehensive loss	(1,290)	(314)
Accumulated deficit	(1,012,721)	(882,284)
Total stockholders' equity	<u>136,759</u>	<u>242,036</u>
Total liabilities and stockholders' equity	<u>\$ 357,284</u>	<u>\$ 461,658</u>

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
REVENUES:				
Product revenue, net	\$ 22,629	\$ 980	\$ 37,176	\$ 980
OPERATING EXPENSES:				
Cost of sales - product	1,603	105	2,691	105
Cost of sales - intangible amortization	200	-	399	-
Research and development	26,324	19,652	49,175	39,179
Selling, general, and administrative	48,579	50,121	96,605	88,220
Other operating expense	10,801	-	10,801	-
Loss from operations	(64,878)	(68,898)	(122,495)	(126,524)
OTHER (EXPENSE) INCOME:				
Other income (expense)	171	(97)	66	(17)
Interest expense	(5,683)	-	(11,248)	-
Interest income	1,508	557	3,240	1,164
NET LOSS	\$ (68,882)	\$ (68,438)	\$ (130,437)	\$ (125,377)
OTHER COMPREHENSIVE LOSS:				
Unrealized gain (loss) from available-for-sale debt securities	192	(32)	(976)	(69)
COMPREHENSIVE LOSS	\$ (68,690)	\$ (68,470)	\$ (131,413)	\$ (125,446)
LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS - BASIC AND DILUTED:				
	\$ (68,882)	\$ (68,438)	\$ (130,437)	\$ (125,377)
LOSS PER SHARE:				
Basic and diluted	\$ (1.52)	\$ (1.58)	\$ (2.89)	\$ (2.90)
WEIGHTED AVERAGE SHARES:				
Basic and diluted	45,430,678	43,410,053	45,185,588	43,300,243

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,	
	2018	2017	2018	2017
Net loss reconciliation:				
GAAP net loss	\$ (68,882)	\$ (68,438)	\$ (130,437)	\$ (125,377)
Intangible amortization	200	-	399	-
Stock-based compensation expense	8,020	11,461	15,570	20,533
Restructuring charges	1,400	-	1,400	-
Non-cash interest	3,390	-	6,668	-
Ipsen payment	10,801	-	10,801	-
Non-GAAP net loss	<u>\$ (45,071)</u>	<u>\$ (56,977)</u>	<u>\$ (95,599)</u>	<u>\$ (104,844)</u>
Reconciliation of diluted loss per share:				
GAAP loss per share	\$ (1.52)	\$ (1.58)	\$ (2.89)	\$ (2.90)
Intangible amortization	0.01	-	0.01	-
Stock-based compensation expense	0.18	0.27	0.34	0.48
Restructuring charges	0.03	-	0.03	-
Non-cash interest	0.07	-	0.15	-
Ipsen payment	0.24	-	0.24	-
Non-GAAP loss per share	<u>\$ (0.99)</u>	<u>\$ (1.31)</u>	<u>\$ (2.12)</u>	<u>\$ (2.42)</u>
Reconciliation of shares used in loss per share calculation:				
GAAP shares used in loss per share	45,430,678	43,410,053	45,185,588	43,300,243
Non-GAAP dilutive share adjustments	-	-	-	-
Non-GAAP shares used in loss per share	<u>45,430,678</u>	<u>43,410,053</u>	<u>45,185,588</u>	<u>43,300,243</u>

Webcast and Conference Call

In connection with today's reporting of Second Quarter Financial Results, Radius will host a conference call and live audio webcast at 8:00 a.m. ET today, August 7, 2018, to discuss the commercial outlook for TYMLOS, review the financial results and provide a Company update.

Conference Call Information:

Date: Tuesday, August 7, 2018

Time: 8:00 a.m. ET

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

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

Conference ID: 2768066

Live webcast: <https://edge.media-server.com/m6/p/mjedziot>

For those unable to participate in the conference call or webcast, a replay will be available from August 7, 2018 at 11:00 a.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 2768066.

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.

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: 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 regarding Radius' operating performance. 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 and six months ended June 30, 2017 and 2018 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 in the areas of osteoporosis and oncology. 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 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.

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. Radius also is developing abaloparatide-patch based on 3M Company's patented Microstructured Transdermal System technology for potential use as a treatment for postmenopausal women with osteoporosis.

About ACTIVE and ACTIVEExtend

The Phase 3 ACTIVE (Abaloparatide Comparator Trial In Vertebral Endpoints) trial was a randomized, double-blind, placebo-controlled, comparative, multicenter, 18 month international study in 2,463 postmenopausal women with osteoporosis designed to evaluate the efficacy and safety of abaloparatide-SC 80 mcg to reduce the risk of vertebral and nonvertebral fractures. The results of ACTIVE were published in the Journal of the American Medical Association in August of 2016. ACTIVEExtend, an extension of ACTIVE, enrolled patients who had completed 18 months of abaloparatide-SC or placebo in ACTIVE to receive up to 24 additional months of open-label alendronate. The results of ACTIVEExtend were published in the Journal of Clinical Endocrinology & Metabolism (JCEM) in May 2018.

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 women 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.

About RAD140

RAD140 is a non-steroidal selective androgen receptor modulator (SARM). The androgen receptor (AR) is frequently expressed in many estrogen receptor (ER)-positive, ER-negative, and triple-negative breast cancers. Because of its receptor and tissue selectivity, potent activity, oral bioavailability, and long half-life, RAD140 could have clinical potential in the treatment of breast cancer. RAD140 resulted from an internal drug discovery program focused on the androgen receptor pathway and exhibits a differentiated mechanism of action compared to ER-targeted therapy.

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 regarding commercialization of TYMLOS in the U.S., including regarding capturing a share of the U.S. anabolic osteoporosis market and regarding growth of the anabolic market; our efforts to make abaloparatide-SC available outside the U.S.; our expectations regarding our regulatory submissions, including the timing thereof; our expectations regarding our clinical trials, including the design and timing thereof; our entry into potential collaborations, including the timing thereof; the progress in the development of our product candidates, including abaloparatide-patch, elacestrant (RAD1901) and RAD140; each of the statements under the headings “Anticipated Upcoming Milestones,” and “Expected Radius Presentations at Upcoming Conferences in Q3 2018;” the sufficiency of our cash, cash equivalents, restricted cash, marketable securities and investments 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: we expect to need to raise additional funding, which may not

be available; risks related to raising additional capital; 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 and any collaboration 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, 2017 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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