Revance Reports Second Quarter 2020 Financial Results, Provides Corporate Update

August 6, 2020

- Conference call and webcast today at 4:30 p.m. ET -

NEWARK, Calif.--(BUSINESS WIRE)--Aug. 6, 2020-- Revance Therapeutics, Inc. (Nasdaq: RVNC), a biotechnology company focused on innovative aesthetic and therapeutic offerings, including its investigational neuromodulator product, DaxibotulinumtoxinA for Injection, today reported financial results for the quarter ended June 30, 2020, and provided a corporate update.

Key Second Quarter 2020 and Subsequent Updates

- **Commercial Launch of RHA® Collection of Dermal Fillers On-Track for Third Quarter.** Revance has received product supply (RHA® 2, 3 and 4) from Teoxane SA, initiated its PrevU Early Clinical Experience Program and completed the hiring of its initial field force, with plans to commence sales of the RHA® Collection in September.
- **Completed the Acquisition of HintMD - A Proprietary Fintech Platform for Aesthetic Practices.** In May, Revance announced the signing of a definitive agreement to acquire Hint, Inc., a privately held company doing business under the name HintMD, which has created an integrated financial technology (fintech) platform for the aesthetics industry. The acquisition closed on July 23, 2020 and integration is underway. The commercial launch of the HintMD fintech platform, concurrent with the RHA® Collection, is planned for September.
- **Announced Positive Results in Two Phase 2a Studies of DaxibotulinumtoxinA for Injection for the Treatment of Forehead Lines and Crow's Feet, Respectively.** In June, Revance announced results for two Phase 2a open-label, dose escalation studies of its investigational drug candidate DaxibotulinumtoxinA for Injection in the treatment of dynamic forehead lines (FHL) following glabellar (frown) line injections and lateral canthal lines (LCL), commonly known as crow's feet. The studies evaluated a range of doses and, while not powered to provide clinical significance, at least one dose in each study demonstrated a measurable treatment effect (defined as at least a one-point change from baseline in wrinkle severity as assessed by the investigator) in 100% of subjects at 4 weeks, with median duration (defined as the median time to return to baseline wrinkle severity based on both investigator and patient assessment) of 27 weeks in forehead lines and 24 weeks in crow's feet.
- **DaxibotulinumtoxinA for Injection potential November approval in glabellar lines.** In February of this year, the company received U.S. Food and Drug Administration (FDA) notification that its Biologics License Application (BLA) for DaxibotulinumtoxinA for Injection in the treatment of moderate to severe glabellar (frown) lines was accepted for review. Revance has been given a target action date under the Prescription Drug User Fee Act (PDUFA) of November 25, 2020.
- **Completed enrollment in the ASPEN-OLS Phase 3 Open-Label, Long-Term Safety Trial.** Revance's ASPEN Phase 3 clinical program consists of two trials to evaluate the safety and efficacy of DaxibotulinumtoxinA for Injection for the treatment of cervical dystonia in adults: ASPEN-1 and ASPEN-OLS. In June, Revance completed enrollment in its ASPEN-OLS long-term safety trial with a total of 358 subjects. Enrollment in the pivotal trial, ASPEN-1, was completed in October 2019 and is on-track to have topline results reported in the fall of 2020.
- **Topline Results for Phase 2 Plantar Fasciitis Trial on Track for Fall Readout.** In March, Revance announced that its Phase 2 study of DaxibotulinumtoxinA for Injection in plantar fasciitis was fully enrolled, with all subjects dosed and past the primary endpoint visit. The company expects to report topline results from this placebo-controlled study in fall 2020.
- **Enrolled Last Patient in Modified JUNIPER Phase 2 Upper Limb Spasticity Trial.** In June, Revance announced its decision to complete enrollment in its JUNIPER Phase 2 trial of DaxibotulinumtoxinA for Injection for the treatment of upper limb spasticity in adults after stroke or traumatic brain injury. Due to ongoing COVID-19 concerns related to subject enrollment and scheduling in-person study visits, the company chose to end screening and complete the study with 83 subjects enrolled. Revance now expects to announce topline data from the JUNIPER Phase 2 trial in early 2021.
- **Revance and Mylan to Advance Development Program for Biosimilar to BOTOX®.** In June, Revance announced Mylan's decision to move forward with a development plan, under a 351(k) pathway, for a proposed biosimilar to BOTOX® and BOTOX® Cosmetic (onabotulinumtoxinA). With Mylan's decision to move forward with the development program, a milestone payment of $30 million was made to Revance by Mylan in the second quarter.

"The second quarter was a transformational period for the company, marked by many significant accomplishments, despite the challenges resulting

from the COVID-19 pandemic. Of particular note was the acquisition of HintMD, which provides us with an exciting and complementary fintech platform that will meaningfully enhance our ability to partner with aesthetic practices, deliver incremental value, and provide Revance with a healthy source of recurring revenue," said Mark Foley, President and Chief Executive Officer. "Looking ahead to the second half of 2020, we enter a catalyst-rich period, beginning with the planned commercial launch of our RHA® Collection of dermal fillers and the HintMD fintech platform in September. Then, in the fall, we plan to report the topline results from our ASPEN-1 Phase 3 cervical dystonia trial and Phase 2 plantar fasciitis study. Lastly, we remain on track for potential U.S. regulatory approval of DaxibotulinumtoxinA for Injection, in the treatment of glabellar lines, in November. As we make the transition from a pre-commercial to a commercial entity, I am incredibly excited about our future and firmly believe that we have the right people, products and strategy in place to successfully compete in both the aesthetic and therapeutic markets."

Financial Highlights

Cash, cash equivalents and short-term investments as of June 30, 2020 were $494.0 million.

Revenue for the quarter ended June 30, 2020 was $0.3 million with no revenue recognized in the same period in 2019. Revenue for the six months ended June 30, 2020 was $0.4 million compared to $0.3 million for the same period in 2019. Revenue recognized for the quarter consists of both the initial sale of the RHA® Collection of dermal fillers in connection with the PrevU Program and activities related to the Mylan collaboration for the biosimilar to BOTOX® program.

Cost of revenue (exclusive of amortization) for the quarter is minimal and is related to cost of RHA® Collection inventory delivered as part of the PrevU Program.

Research and development expenses for the three and six months ended June 30, 2020 were $27.1 million and $66.9 million compared to $25.5 million and $49.5 million for the same periods in 2019, respectively. A non-cash acquisition charge of $11.2 million was allocated to in-process research and development from the TEOXANE distribution agreement in the first quarter of 2020.

Selling, general and administrative expenses for the three and six months ended June 30, 2020 were $29.6 million and $50.8 million compared to $13.6 million and $26.5 million for the same periods in 2019, respectively. The increase in selling, general and administrative expenses is primarily due to increased costs related to commercial activities, HintMD acquisition related costs, human capital, and infrastructure build-out.

Total operating expenses for the three and six months ended June 30, 2020 were $57.4 million and $118.4 million compared to $39.1 million and $76.0 million for the same periods in 2019, respectively. Depreciation and amortization for the three and six months ended June 30, 2020 was $1.4 million and $2.2 million, respectively. Stock-based compensation for the three and six months ended June 30, 2020 was $7.4 million and $13.9 million, respectively. When excluding depreciation and amortization, stock-based compensation, and non-cash in-process research and development, total operating expenses for the three and six months ended June 30, 2020 were $48.6 million and $91.2 million, respectively.

Net loss for the three and six months ended June 30, 2020 was $60.6 million and $122.5 million compared to $37.4 million and $72.7 million for the same periods in 2019, respectively.

Near-Term Milestone Expectations

Aesthetics:

- Commercial launch of HintMD and RHA® Collection of dermal fillers expected in September 2020.
- Topline results from Phase 2 open-label, dose-escalation study of DaxibotulinumtoxinA for Injection in upper facial lines expected in 4Q 2020.
- Prescription Drug User Fee Act (PDUFA) date of November 25, 2020, for potential U.S. Food and Drug Administration (FDA) approval of DaxibotulinumtoxinA for Injection in glabellar lines.

Therapeutics:

- Topline results from ASPEN-1 Phase 3 placebo-controlled, parallel-group study of DaxibotulinumtoxinA for Injection in cervical dystonia expected in fall 2020.
- Topline results from Phase 2 placebo-controlled study of DaxibotulinumtoxinA for Injection in plantar fasciitis expected in fall 2020.
- Topline results from JUNIPER Phase 2 placebo-controlled, dose-ranging study of DaxibotulinumtoxinA for Injection in upper limb spasticity expected in early 2021.

2020 Financial Outlook

We are developing our acquisition accounting for HintMD and once completed we can provide GAAP operating expense guidance for 2020. Nevertheless, Revance expects non-GAAP (U.S. generally accepted accounting principles, or GAAP) operating expense, which excludes depreciation and amortization, stock-based compensation, and non-cash in-process research and development costs, to be in the range of $220 to $230 million. With multiple clinical programs underway, along with regulatory and pre-commercial manufacturing activities, Revance anticipates 2020 non-GAAP, non-HintMD related research and development expense to be $95 to $100 million. With current cash and equivalents, management projects that the company is funded into 2023.

Conference Call

Individuals interested in listening to the conference call may do so by dialing (855) 453-3827 for domestic callers, or (484) 756-4301 for international callers and reference conference ID: 4968933; or from the webcast link in the investor relations section of the company's website at: www.revance.com. A replay of the call will be available beginning August 6, 2020 at 4:30 p.m. PT/7:30 p.m. ET to August 7, 2020 at 4:30 p.m. PT/7:30 p.m. ET. To access the replay, dial (855) 859-2056 or (404) 537-3406 and reference conference ID: 4968933.

The live webcast can be accessed here and will be available in the investor relations section on the company's website for 30 days following the completion of the call. In light of reduced call center resources during this time of required social-distancing, Revance requests that listeners who do not plan on participating in the question and answer session listen to the live webcast rather than dialing in by phone.

About Revance Therapeutics, Inc.

Revance Therapeutics, Inc. is a biotechnology company focused on innovative aesthetic and therapeutic offerings, including its next-generation neuromodulator product, DaxibotulinumtoxinA for Injection. DaxibotulinumtoxinA for Injection combines a proprietary stabilizing peptide excipient with a highly purified botulinum toxin that does not contain human or animal-based components. Revance has successfully completed a Phase 3 program for DaxibotulinumtoxinA for Injection in glabellar (frown) lines and is pursuing U.S. regulatory approval in 2020. Revance is also evaluating DaxibotulinumtoxinA for Injection in the full upper face, including glabellar lines, forehead lines and crow's feet, as well as in three therapeutic indications - cervical dystonia, adult upper limb spasticity and plantar fasciitis. To accompany DaxibotulinumtoxinA for Injection, Revance owns a unique portfolio of premium products and services for U.S. aesthetics practices, including the exclusive U.S. distribution rights to the RHA® Collection of dermal fillers, the first and only range of FDA-approved fillers for correction of dynamic facial wrinkles and folds, and the HintMD fintech platform, which includes integrated smart payment, subscription and loyalty digital services. Revance has also partnered with Mylan N.V. to develop a biosimilar to BOTOX®, which would compete in the existing short-acting neuromodulator marketplace. Revance is dedicated to making a difference by transforming patient experiences. For more information or to join our team visit us at www.revance.com.

Forward-Looking Statements

This press release contains forward-looking statements, including statements related to Revance's financial outlook, milestone expectations, expected cash runway and financial performance; the planned commercial launch of our RHA® Collection of dermal fillers and the HintMD fintech platform, the process and timing of, and ability to complete, current and anticipated future clinical development of our investigational drug product candidates; the initiation, design, enrollment, submission, timing and results of our clinical studies, including the near-term milestone expectations described above; development of a biosimilar to BOTOX®; results of our non-clinical programs; statements about our business strategy, timeline and other goals and market for our anticipated products, plans and prospects, including our commercialization plans; statements about our ability to obtain, and the timing relating to, regulatory approval with respect to our drug product candidates, including with respect to the anticipated approval of DaxibotulinumtoxinA for Injection in glabellar lines and expected PDUFA date; and potential benefits of our drug product candidates and our technologies, including with respect to the RHA® line of dermal fillers and HintMD fintech platform.

Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from our expectations. These risks and uncertainties include, but are not limited to: the outcome, cost, and timing of our product development activities and clinical trials; the uncertain clinical development process, including the risk that clinical trials may not have an effective design or generate positive results; our ability to obtain and maintain regulatory approval of our drug product candidates, including our ability to receive timely approval of DaxibotulinumtoxinA for Injection; our ability to obtain funding for our operations; our plans to research, develop, and commercialize our drug product candidates; our ability to achieve market acceptance of our drug product candidates; unanticipated costs or delays in research, development, and commercialization efforts; the applicability of clinical study results to actual outcomes; the size and growth potential of the markets for our drug product candidates; our ability to successfully commercialize our drug product candidates and the timing of commercialization activities and anticipated product launches; the rate and degree of market acceptance of our drug product candidates; our ability to develop sales and marketing capabilities; the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for financing; our ability to continue obtaining and maintaining intellectual property protection for our drug product candidates; and the impact of the COVID-19 pandemic on our manufacturing operations, supply chain, business operations, commercialization efforts, end user demand for our products, clinical trials and other aspects of our business. Detailed information regarding factors that may cause actual results to differ materially from the results expressed or implied by statements in this press release may be found in Revance's periodic filings with the Securities and Exchange Commission (the "SEC"), including factors described in the section entitled "Risks Factors" in the Registration Statement on Form S-4/A filed with the SEC on June 23, 2020. The forward-looking statements in this press release speak only as of the date hereof. Revance disclaims any obligation to update these forward-looking statements.

Use of Non-GAAP Financial Measures

Revance has presented certain non-GAAP financial measures in this release. This release and the reconciliation tables included herein include total non-GAAP operating expense and non-GAAP R&D expense, both of which exclude depreciation and amortization, stock-based compensation, and non-cash in-process research and development costs. Revance excludes depreciation and amortization, stock-based compensation, and non-cash in-process research and development costs because management believes the exclusion of these items is helpful to investors to evaluate Revance's recurring operational performance. Revance management uses these non-GAAP financial measures to monitor and evaluate its operating results and trends on an on-going basis, and internally for operating, budgeting and financial planning purposes. The non-GAAP financial measures should be considered in addition to results prepared in accordance with GAAP but should not be considered a substitute for or superior to GAAP results.

REVANCE THERAPEUTICS, INC.
Condensed Consolidated Balance Sheets
(In thousands, except share and per share amounts)
(Unaudited)

	June 30, 2020	December 31, 2019
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 363,511	$ 171,160

Short-term investments	130,532	118,955
Accounts receivable	49	—
Inventories	778	—
Prepaid expenses and other current assets	7,901	6,487
Total current assets	502,771	296,602
Property and equipment, net	13,695	14,755
Intangible assets, net	31,660	—
Operating lease right of use assets	25,366	26,531
Restricted cash	1,050	730
Other non-current assets	1,639	1,669
TOTAL ASSETS	$ 576,181	$ 340,287
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 6,603	$ 8,010
Accruals and other current liabilities	22,245	18,636
Deferred revenue, current portion	12,255	7,911
Operating lease liabilities, current portion	3,789	3,470
Derivative liability	3,101	2,952
Total current liabilities	47,993	40,979
Convertible senior notes	174,304	—
Deferred revenue, net of current portion	74,295	47,948
Operating lease liabilities, net of current portion	23,871	25,870
TOTAL LIABILITIES	320,463	114,797
STOCKHOLDERS' EQUITY		
Convertible preferred stock, par value $0.001 per share — 5,000,000 shares authorized, and no shares issued and outstanding as of June 30, 2020 and December 31, 2019	—	—
Common stock, par value $0.001 per share — 95,000,000 shares authorized both as of June 30, 2020 and December 31, 2019; 57,313,556 and 52,374,735 shares issued and outstanding as of June 30, 2020 and December 31, 2019, respectively	57	52
Additional paid-in capital	1,222,271	1,069,639
Accumulated other comprehensive income	117	3
Accumulated deficit	(966,727)	(844,204)
TOTAL STOCKHOLDERS' EQUITY	255,718	225,490
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 576,181	$ 340,287

REVANCE THERAPEUTICS, INC.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Revenue	$ 299	$ —	$ 357	$ 278
Operating expenses:				
Cost of revenue (exclusive of amortization)	21	—	21	—
Research and development	27,103	25,526	66,897	49,521
Selling, general and administrative	29,606	13,596	50,830	26,506
Amortization	674	—	674	—
Total operating expenses	57,404	39,122	118,422	76,027
Loss from operations	(57,105)	(39,122)	(118,065)	(75,749)
Interest income	964	1,596	2,455	3,166
Interest expense	(4,256)	—	(6,404)	—
Changes in fair value of derivative liability	(59)	21	(149)	(71)
Other income (expense), net	(134)	115	(260)	(40)
Loss before income taxes	(60,590)	(37,390)	(122,423)	(72,694)
Income tax provision	—	—	(100)	—
Net loss	(60,590)	(37,390)	(122,523)	(72,694)
Unrealized gain (loss) and adjustment on securities included in net loss	(407)	46	114	124
Comprehensive loss	$ (60,997)	$ (37,344)	$ (122,409)	$ (72,570)
Basic and diluted net loss	$ (60,590)	$ (37,390)	$ (122,523)	$ (72,694)

Basic and diluted net loss per share	$ (1.12)	$ (0.86)	$ (2.27)	$ (1.71)
Basic and diluted weighted-average number of shares used in computing net loss per share	54,257,320	43,260,317	54,062,678	42,434,137

REVANCE THERAPEUTICS, INC.
Reconciliation of GAAP Operating Expense to Non-GAAP Operating Expense
(In thousands)
(Unaudited)

	Three Months Ended June 30, 2020	Six Months Ended June 30, 2020
Operating expense:		
GAAP operating expense	$ 57,404	$ 118,422
Adjustments:		
In-process research and development	—	(11,184)
Stock-based compensation	(7,353)	(13,897)
Depreciation and amortization	(1,413)	(2,152)
Non-GAAP operating expense	$ 48,638	$ 91,189

REVANCE THERAPEUTICS, INC.
Reconciliation of GAAP R&D Expense to Non-GAAP R&D Expense
(In thousands)
(Unaudited)

	Three Months Ended June 30, 2020	Six Months Ended June 30, 2020
R&D expense:		
GAAP R&D expense	$ 27,103	$ 66,897
Adjustments:		
In-process research and development	—	(11,184)
Stock-based compensation	(2,584)	(5,026)
Depreciation and amortization	(503)	(1,000)
Non-GAAP R&D expense	$ 24,016	$ 49,687

View source version on businesswire.com: https://www.businesswire.com/news/home/20200806005875/en/

Investors
Revance Therapeutics, Inc.:
Jeanie Herbert, 714-325-3584
jherbert@revance.com
or
Gilmartin Group, LLC.:
Laurence Watts, 619-916-7620
laurence@gilmartinir.com

Media
Revance Therapeutics, Inc.:
Sara Fahy, 949-887-4476
sfahy@revance.com
or
General Media:
Y&R:
Jenifer Slaw, 347-971-0906
jenifer.slaw@YR.com
or
Trade Media:
Nadine Tosk, 504-453-8344
nadinepr@gmail.com

Source: Revance Therapeutics, Inc.