Castle Biosciences Announces Fourth Quarter and Full-Year 2020 Results

March 8, 2021

Full-year 2020 revenues of $62.6 million, up 21% compared to 2019

Full-year 2020 dermatology test report volume up 8% compared to 2019

Full-year 2020 gross margin of 85%

Earlier today, the Company launched Integrated DecisionDx-Melanoma Test Result, Utilizing AI to Predict Individualized Risk

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

FRIENDSWOOD, Texas--(BUSINESS WIRE)--Mar. 8, 2021-- Castle Biosciences, Inc. (Nasdaq: CSTL), a skin cancer diagnostics company providing personalized genomic information to improve cancer treatment decisions, today announced its financial results for the fourth quarter and twelve months ended Dec. 31, 2020.

"Our execution in 2020 allowed us to successfully navigate through this unique year and further our position as the leader in genomic testing for dermatologic cancers," said Derek Maetzold, president and chief executive officer of Castle Biosciences. "We began the year with one skin cancer test and ended the year with a suite of three tests, more than tripling our estimated in-market U.S. total addressable market (TAM) to $2 billion.

"DecisionDx®-Melanoma, DecisionDx® DiffDx™- Melanoma and DecisionDx®-SCC, our tests for cutaneous melanoma, suspicious pigmented lesions and high-risk cutaneous squamous cell carcinoma, respectively, are each designed to provide actionable information for dermatology clinicians, which helps to guide cancer management decisions and improve patient outcomes.

"We are now entering the next chapter of our growth story. Earlier today, we announced clinical availability of an artificial intelligence-based integrated DecisionDx-Melanoma test result – integrating meaningful clinical and pathologic features with tumor biology identified by our DecisionDx-Melanoma test – designed to provide a more precise prediction of risk. Further, we are developing several pipeline tests that are focused on answering clinical questions with high unmet need along the patient care continuum. We estimate these pipeline tests could add an additional $3.6 billion to our U.S. TAM, bringing our aggregate U.S. TAM to slightly more than $5.5 billion."

Twelve Months Ended December 31, 2020, Financial Highlights

- Revenues were $62.6 million, a 21% increase compared to $51.9 million during the same period in 2019. Included in revenue for the period were positive revenue adjustments related to tests delivered in prior periods. These positive prior period revenue adjustments for the twelve months ended Dec. 31, 2020, were $0.2 million, compared to $2.5 million for the same period in 2019.
- Total gene expression profile test reports delivered in 2020 were 18,185, compared to 17,055 in 2019:
  - DecisionDx-Melanoma test reports delivered in 2020 were 16,232, compared to 15,529 in 2019. Third-party data for 2020 suggests that diagnoses of melanoma were down more than 20% over the prior year.
  - DecisionDx-SCC test reports delivered in 2020 (Aug. 31, 2020 – Dec. 31, 2020) were 485.
  - DecisionDx DiffDx-Melanoma test reports delivered in 2020 (Nov. 2, 2020 - Dec. 31, 2020) were 73.
  - DecisionDx-UM test reports delivered in 2020 were 1,395, compared to 1,526 in 2019.
- Gross margin for the twelve months ended Dec. 31, 2020, was 85%.
- Operating cash flow was $9.9 million, compared to $7.0 million for the same period in 2019.
- Adjusted operating cash flow, excluding the effects of certain relief payments described below, was $1.5 million, compared to $7.0 million for the same period in 2019.

Cash and Cash Equivalents

As of Dec. 31, 2020, the Company's cash and cash equivalents totaled $410 million.

Fourth Quarter Ended December 31, 2020, Financial Highlights

- Revenues were $17.3 million in the fourth quarter of 2020, compared to $17.6 million in the fourth quarter of 2019. Included in revenue for the quarters were positive revenue adjustments related to tests delivered in prior periods. These positive prior period revenue adjustments for the three months ended Dec. 31, 2020, were $3.5 million, compared to $4.3 million for the same period in 2019.
- Delivered 5,157 total gene expression profile test reports in the fourth quarter of 2020, compared to 4,914 in the same period in 2019:
  - DecisionDx-Melanoma test reports delivered in the quarter were 4,246, compared to 4,480 in the same period in 2019.
  - DecisionDx-SCC test reports delivered in the quarter were 428.

- DecisionDx DiffDx-Melanoma test reports delivered from Nov. 2 through Dec. 31, 2020, were 73.
- DecisionDx®-UM test reports delivered in the quarter were 410, compared to 434 in the same period in 2019.
- Gross margin in the fourth quarter of 2020 was 85%.
- Operating cash flow was $(0.4) million in the fourth quarter of 2020, compared to $4.5 million in the fourth quarter of 2019.
- Adjusted operating cash flow, excluding the effects of certain relief payments described below, was $1.5 million in the fourth quarter of 2020, compared to $4.5 million in the fourth quarter of 2019.

Recent Clinical Evidence Highlights

- On March 8, 2021, the Company announced clinical availability of an artificial intelligence-based integrated DecisionDx-Melanoma test result. The Company validated the integration of clinicopathologic features with the tumor biology insights provided by the DecisionDx-Melanoma test. The integrated test result (ITR) is designed to provide a more precise risk prediction to further improve the clinical actionability by clinicians and their patients in helping to guide cancer management decisions. For more information, see the Company's news release from earlier today.
- In January 2021, the Company presented data on DecisionDx-Melanoma and DecisionDx DiffDx-Melanoma at the 18th Annual Winter Clinical Dermatology Conference:
  - The virtual poster for DecisionDx-Melanoma was entitled, "Identifying predictors of sentinel lymph node metastasis in cutaneous melanoma patients using molecular and clinicopathologic high-risk features." For 3,093 patients with T1-T4 cutaneous melanoma, authors used decision tree analysis to determine which molecular and clinicopathologic features best stratify sentinel lymph node (SLN) positivity risk and demonstrated that DecisionDx-Melanoma was the most important feature in distinguishing between high and low SLN-positivity rates (p<0.001).
  - The virtual poster for DecisionDx DiffDx-Melanoma was entitled, "Performance of a 35-gene expression profile test in suspicious pigmented lesions of the head and neck." The study evaluated DecisionDx DiffDx-Melanoma's accuracy in classifying pigmented lesions on the head and neck. The data demonstrated that DecisionDx DiffDx-Melanoma has the ability to be an effective tool for refining melanoma diagnoses on the head and neck and therefore improving downstream management decisions, as indicated by its high sensitivity and specificity in the study.
- Also in January 2021, the Company presented data at the Maui Derm for Dermatologists 2021 conference:
  - The virtual poster for DecisionDx-SCC was entitled, "Clinical utility of the 40-gene expression profile (40-GEP) for improved patient management decisions and disease related outcomes when combined with current clinicopathological risk factors for cutaneous squamous cell carcinoma (cSCC): Case Series." Two SCC cases were presented that highlight DecisionDx-SCC's utility in stratifying risk in SCC. The cases had very similar risk of metastasis at diagnosis as both presented with a history of immunosuppression and had identical staging (T2a per Brigham and Women's Hospital staging; T1 per American Joint Committee on Cancer staging), but had divergent outcomes:
    - Case 1 did not recur, despite incomplete resection. This case had a low-risk (Class 1) DecisionDx-SCC result, consistent with the clinical outcome of no clinical progression.
    - Case 2 developed local recurrence and regional metastasis, and eventually died from SCC, despite clear surgical margins. This case had a highest-risk (Class 2B) DecisionDx-SCC result, consistent with clinical progression. The study authors concluded that incorporating DecisionDx-SCC as a prognostic factor with traditional clinicopathologic risk factors can improve stratification of high-risk SCC patients with at least one risk factor, thereby informing risk-appropriate management strategies.
- In February 2021, the Company presented data on DecisionDx-Melanoma at the 19th Annual South Beach Symposium:
  - The first poster was entitled, "31-Gene expression profiling improves risk stratification in patients with T1 cutaneous melanoma." Univariate analysis of the study data showed DecisionDx-Melanoma to be a stronger predictor of recurrence-free survival (RFS) than SLN status. Additionally, multivariable analysis showed DecisionDx-Melanoma to be a strong, independent predictor of RFS. With Class 2B RFS status similar to SLN positive status, Class 2B patients warrant follow-up strategies similar to SLN positive patients.
  - The second DecisionDx-Melanoma poster was entitled, "The clinical and financial impact of the 31-gene expression profile testing on sentinel lymph node biopsy patients selection in patients with T1b cutaneous melanoma." The authors analyzed all clinical DecisionDx-Melanoma tests that were reported from Jan. 3, 2019 through Sept. 4, 2020. The data showed that 75% of eligible patients with T1b tumors had a Class 1A result and could potentially forego sentinel lymph node biopsy (SLNB). The authors estimate that foregoing SLNB in these patients could reduce healthcare expenditures by up to $120 million in SLNB-related costs.
- For a summary of Castle's 2020 business and clinical evidence highlights, please see the Company's news release from Jan. 13, 2021. Find the release here: [Castle Biosciences Announces Preliminary Fourth Quarter and Full Year 2020 Results](#).

Conference Call and Webcast Details

Castle Biosciences will hold a conference call on Monday, March 8, 2021, at 4:30 p.m. Eastern time to discuss its fourth quarter and full-year 2020

results and provide a corporate update.

A live webcast of the conference call can be accessed here: https://edge.media-server.com/mmc/p/9pwwmi9c or via the webcast link on the Investor Relations page of the Company's website (www.castlebiosciences.com). Please access the webcast at least 10 minutes before the conference call start time. An archive of the webcast will be available on the Company's website until March 29, 2021.

To access the live conference call via phone, please dial 877-282-2581 from the United States and Canada, or +1 470-495-9479 internationally, at least 10 minutes prior to the start of the call, using the conference ID 3834669.

There will be a brief Question & Answer session following management commentary.

Use of Non-GAAP Financial Measures (UNAUDITED)

In this release, we use the metric of Adjusted Operating Cash Flow, which is a non-GAAP financial measure and is not calculated in accordance with generally accepted accounting principles in the United States (GAAP). This non-GAAP financial measure reflects adjustments to net cash provided by operating activities to remove the effects of two payments we received associated with government aid to healthcare providers due to COVID-19, which we believe are not indicative of our ongoing operations.

We use Adjusted Operating Cash Flow internally because we believe this metric provides useful supplemental information in assessing our cash flow performance from our core ongoing business activities by removing the effects of these items on our operating cash flows. We believe this metric is also useful to investors as a supplement to GAAP measures in analyzing the performance of our business. However, this non-GAAP financial measure may be different from non-GAAP financial measures used by other companies, even when the same or similarly titled terms are used to identify such measures, limiting their usefulness for comparative purposes. This non-GAAP financial measure is not meant to be a substitute for net cash provided by (used in) operating activities reported in accordance with GAAP and should be considered in conjunction with our financial information presented on GAAP basis. Accordingly, investors should not place undue reliance on non-GAAP financial measures. Reconciliations of this non-GAAP financial measure to the most directly comparable GAAP financial measure are presented in the table at the end of this press release.

About Castle Biosciences

Castle Biosciences (Nasdaq: CSTL) is a commercial-stage dermatologic cancer company focused on providing physicians and their patients with personalized, clinically actionable genomic information to make more accurate treatment decisions. The Company currently offers tests for patients with cutaneous melanoma (DecisionDx®-Melanoma, DecisionDx®-CM*Seq),* cutaneous squamous cell carcinoma (DecisionDx®-SCC), suspicious pigmented lesions (DecisionDx® DiffDx™-Melanoma) and uveal melanoma (DecisionDx®-UM, DecisionDx®-PRAME and DecisionDx®-UM*Seq*). For more information about Castle's gene expression profile tests, visit www.CastleTestInfo.com. Castle also has active research and development programs for tests in other dermatologic diseases with high clinical need. Castle Biosciences is based in Friendswood, Texas (Houston), and has laboratory operations in Phoenix, Arizona. For more information, visit www.CastleBiosciences.com.

DecisionDx-Melanoma, DecisionDx-CM*Seq*, DecisionDx-SCC, DecisionDx DiffDx-Melanoma, DecisionDx-UM, DecisionDx-PRAME and DecisionDx-UM*Seq* and are trademarks of Castle Biosciences, Inc.

Forward-Looking Statements

The information in this press release contains forward-looking statements and information within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the "safe harbor" created by those sections. These forward-looking statements include, but are not limited to, statements concerning the effects of the COVID-19 pandemic on our business and our efforts to address its impact on our business, statements concerning the estimated size of our total addressable market or our existing and pipeline products, the impact of our tests, including DecisionDx-Melanoma, DecisionDx-SCC and DecisionDx DiffDx-Melanoma, on patient treatment plans, our prospects and plans and the objectives of management. The words "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions, or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. These forward-looking statements involve risks and uncertainties that could cause our actual results to differ materially from those in the forward-looking statements, including, without limitation, the effects of the COVID-19 pandemic on our business and our efforts to address its impact on our business, the timing and amount of revenue we are able to recognize in a given fiscal period, the level and availability of reimbursement for our products, our ability to manage our anticipated growth and the risks set forth in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, filed with the SEC on November 9, 2020, and in our other filings with the SEC. The forward-looking statements are applicable only as of the date on which they are made, and we do not assume any obligation to update any forward-looking statements, except as may be required by law.

The COVID-19 situation continues to evolve and brings along with it a high level of uncertainty surrounding potential future impacts. Therefore, trends in test report volumes, order data and new ordering clinician data is not necessarily indicative of the Company's results of operations that can be expected for future interim periods or for the year ending December 31, 2021.

CASTLE BIOSCIENCES, INC.
CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE (LOSS) INCOME
(in thousands, except per share data)

	Three Months Ended December 31,				Twelve Months Ended December 31,			
	2020		2019		2020		2019	
	(unaudited)		(unaudited)		(unaudited)			
NET REVENUES	$	17,299	$	17,635	$	62,649	$	51,865
COST OF SALES		2,673		2,011		9,685		7,310

	Three months ended		Twelve months ended	
Gross margin	14,626	15,624	52,964	44,555
OPERATING EXPENSES AND OTHER OPERATING INCOME				
Research and development	4,581	3,159	13,256	7,385
Selling, general and administrative	14,959	9,852	48,132	29,842
Other operating income[1]	(1,882)	—	(1,882)	—
Total operating expenses, net	17,658	13,011	59,506	37,227
Operating (loss) income	(3,032)	2,613	(6,542)	7,328
Interest income	19	280	373	312
Interest expense	(395)	(766)	(2,634)	(4,571)
(Loss) gain on extinguishments of debt	(1,397)	—	(1,397)	5,213
Other expense, net	—	—	—	(2,933)
(Loss) income before income taxes	(4,805)	2,127	(10,200)	5,349
Income tax expense	84	72	84	72
Net (loss) income and comprehensive (loss) income	(4,889)	2,055	(10,284)	5,277
Convertible preferred stock cumulative dividends	—	—	—	2,156
Accretion of redeemable convertible preferred stock to redemption value	—	—	—	130
Net (loss) income and comprehensive (loss) income attributable to common stockholders	$ (4,889)	$ 2,055	$ (10,284)	$ 2,991
(Loss) earnings per share attributable to common stockholders:				
Basic	$ (0.23)	$ 0.12	$ (0.54)	$ 0.35
Diluted	$ (0.23)	$ 0.11	$ (0.54)	$ (0.21)
Weighted-average shares outstanding:				
Basic	20,833	17,295	18,929	8,584
Diluted	20,833	18,600	18,929	8,658

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1   For the three and twelve months ended December 31, 2020, reflects the recognition of other income associated with relief funds we originally received from the U.S. Department of Health and Human Services (HHS) in April 2020.

CASTLE BIOSCIENCES, INC.
CONDENSED BALANCE SHEETS
(in thousands)

	December 31,	
	2020	2019
	(unaudited)	
ASSETS		
Current Assets		
Cash and cash equivalents	$ 409,852	$ 98,845
Accounts receivable, net	12,759	14,648
Inventory	2,217	1,237
Prepaid expenses and other current assets	4,766	1,951
Total current assets	429,594	116,681
Long-term accounts receivable, net	1,096	870
Property and equipment, net	7,102	2,060
Other assets – long-term	1,536	135
Total assets	$ 439,328	$ 119,746
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable	$ 2,098	$ 1,865
Accrued compensation	9,108	5,779
Medicare advance payment	6,615	—
Other accrued liabilities	3,055	1,812
Current portion of long-term debt	—	5,833
Total current liabilities	20,876	15,289
Long-term debt	—	19,289
Noncurrent portion of Medicare advance payment	1,735	—
Deferred rent and other liabilities	1,026	55

Total liabilities		23,637	34,633
Stockholders' Equity			
Common stock		25	17
Additional paid-in capital		478,162	137,308
Accumulated deficit		(62,496)	(52,212)
Total stockholders' equity		415,691	85,113
Total liabilities and stockholders' equity	$	439,328	$ 119,746

CASTLE BIOSCIENCES, INC.
CONDENSED STATEMENTS OF CASH FLOWS
(in thousands)

		Twelve Months Ended December 31,	
		2020	**2019**
OPERATING ACTIVITIES		(unaudited)	
Net (loss) income	$	(10,284)	$ 5,277
Adjustments to reconcile net (loss) income to net cash provided by operating activities:			
Depreciation		472	354
Stock compensation expense		8,309	1,249
Amortization of intangibles		—	4
Amortization of debt discounts and issuance costs		839	1,925
Other non-cash interest		—	442
Loss (gain) on extinguishment of debt		1,397	(5,213)
Change in fair value of preferred stock warrant liability		—	619
Change in fair value of embedded derivative		—	237
Change in fair value of convertible promissory note accounted for under the fair value option		—	2,077
Other		(16)	—
Change in operating assets and liabilities:			
Accounts receivable		1,663	(896)
Prepaid expenses and other current assets		(2,815)	(1,276)
Inventory		(980)	(355)
Other assets		(1,401)	(85)
Accounts payable		169	557
Accrued compensation		3,329	1,208
Medicare advance payment		8,350	—
Other accrued liabilities		561	879
Deferred rent and other liabilities		272	12
Net cash provided by operating activities		9,865	7,015
INVESTING ACTIVITIES			
Purchases of property and equipment		(4,751)	(937)
Proceeds from sale of property and equipment		3	—
Net cash used in investing activities		(4,748)	(937)
FINANCING ACTIVITIES			
Proceeds from public offerings of common stock, net of underwriting discounts, commissions and offering costs		330,041	65,931
Proceeds from exercise of preferred stock warrants		—	49
Proceeds from issuance of convertible promissory notes, net of issuance costs		—	11,695
Proceeds from issuance of convertible promissory note and common stock warrant, net of issuance costs		—	9,236
Proceeds from issuance of term debt, net of issuance costs		—	1,776
Repayments on term debt		(27,359)	—
Repayments on line of credit		—	(1,791)
Proceeds from exercise of common stock options		1,593	1,174
Proceeds from contributions to the employee stock purchase plan		1,615	218
Net cash provided by financing activities		305,890	88,288
NET CHANGE IN CASH AND CASH EQUIVALENTS		311,007	94,366
Beginning of period		98,845	4,479
End of period	$	409,852	$ 98,845

CASTLE BIOSCIENCES, INC.

Reconciliation of Non-GAAP Financial Measures (UNAUDITED)

The table below presents the reconciliation of adjusted operating cash flow, which is a non-GAAP measure. See "Use of Non-GAAP Financial Measures (UNAUDITED)" above for further information regarding the Company's use of non-GAAP financial measures.

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2020	2019	2020	2019
(in thousands)				
Adjusted operating cash flow				
Net cash (used in) provided by operating activities (GAAP)	$ (430)	$ 4,493	$ 9,865	$ 7,015
Medicare advance payment[1]	—	—	(8,350)	—
HHS provider relief funds[2]	1,882	—	—	—
Adjusted operating cash flow (Non-GAAP)	$ 1,452	$ 4,493	$ 1,515	$ 7,015

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[1] In April 2020, we received an advance payment of $8.3 million from the Centers for Medicare & Medicaid Service (CMS), which will be applied against future Medicare claims that we submit for reimbursement beginning in April 2021. Originally, recoupment was to begin in August 2020, but recent legislation amended the recoupment schedule such that recoupment will begin in April 2021 and continue for a period of up to 17 months. We recorded the receipt of the payment as a liability on our balance sheet and, in accordance with GAAP, it is included in net cash provided by operating activities in the period received. We have excluded receipt of the advance payment from adjusted operating cash flow, but as future claims are submitted for reimbursement and applied against this balance, we expect to include the advance payment in adjusted operating cash flow to the extent that Medicare claims submitted for reimbursement have been applied to the balance.

[2] Reflects cash activity in the three months ended December 31, 2020 associated with the HHS provider relief funds.

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