Castle Biosciences Announces Third Quarter 2020 Results

November 9, 2020

Q3 2020 revenues of $15.2 million, Q3 2020 YTD revenues of $45.4 million

DecisionDx-Melanoma report volume returned to quarterly year-over-year increase

Q3 2020 gross margin of 84%

Recently received final expanded positive Medicare coverage for DecisionDx-Melanoma

FRIENDSWOOD, Texas--(BUSINESS WIRE)--Nov. 9, 2020-- 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 third quarter and nine months ended Sept. 30, 2020.

“The Castle team made significant progress on our strategic growth initiatives in the third quarter,” said Derek Maetzold, president and chief executive officer of Castle Biosciences. “We also returned to year-over-year volume growth in DecisionDx®-Melanoma report volume, our current lead revenue driver, despite a reduction in melanoma diagnoses, which we believe is due to COVID-19. We are pleased to see, in October, the posting of the expanded local coverage determination (LCD) and accompanying billing and coding article for our DecisionDx-Melanoma test, with an effective date of November 22, 2020.

“As laid out at the beginning of 2020, we planned to launch our two near-term pipeline tests in the second half of the year. We successfully launched DecisionDx®-SCC, our test for patients diagnosed with cutaneous squamous cell carcinoma (SCC) with one or more high-risk factors, on August 31, leveraging our strong, existing dermatologic sales channels. Through October, we have received 282 orders by 193 clinicians for this prognostic test, of which most were existing customers. Additionally, last week we launched our second new test of 2020, DecisionDx® DiffDx™-Melanoma, for use in patients with suspicious pigmented lesions. We estimate that combined, our three commercially available skin cancer products, DecisionDx-Melanoma, DecisionDx-SCC and DecisionDx DiffDx-Melanoma, have a total addressable U.S. market of approximately $2.0 billion.

“We believe evidence development is key to further support clinician adoption and commercial coverage of our tests. During the quarter, we advanced our clinical studies and saw continued progress with publications of peer-reviewed articles.

“As we look ahead to the remainder of 2020 and into 2021, with our team’s continued commitment to improve patient outcomes, we believe we remain well-positioned for long-term growth and value creation.”

Third Quarter Ended Sept. 30, 2020, Selected Results

- Revenues were $15.2 million in the third quarter of 2020, a 3% increase compared to $14.8 million in the third quarter of 2019. Included in revenue for the quarter were positive revenue adjustments related to tests delivered in prior periods of $1.5 million, compared to positive adjustments of $3.2 million for the quarter ended Sept. 30, 2019.
- Delivered 4,404 DecisionDx-Melanoma test reports in the third quarter of 2020, a 7% increase compared to the 4,126 reports delivered in the third quarter of 2019, despite a reduction in melanoma diagnoses, which the Company believes is due to the ongoing impacts of COVID-19.
- Delivered 318 DecisionDx-UM test reports in the third quarter of 2020, compared to 356 reports in the third quarter of 2019. The Company believes this decrease is the result of fewer patient visits to physicians during the quarter due to the COVID-19 pandemic.
- The Company’s DecisionDx-SCC test became commercially available on Aug. 31, 2020. For the period of Aug. 31, 2020 through Sept. 30, 2020, the Company delivered 57 DecisionDx-SCC test reports.
- Gross margin in the third quarter of 2020 was 84%.
- Operating cash flow was $(3.0) million in the third quarter of 2020, compared to $0.8 million in the third quarter of 2019.

Nine Months Ended Sept. 30, 2020, Selected Results

- Revenues were $45.4 million, a 32% increase compared to $34.2 million during the same period in 2019. Included in revenue for the period were positive revenue adjustments related to tests delivered in prior periods. For the nine months ended Sept. 30, 2020 and 2019, these amounts totaled $0.2 million and $2.4 million, respectively.
- Delivered 11,986 DecisionDx-Melanoma test reports, an increase of 8% over the same period in 2019.
- Delivered 985 DecisionDx-UM test reports, a decrease of 10% over the same period in 2019.
- Gross margin for the nine months ended Sept. 30, 2020, was 85%.
- Operating cash flow was $10.3 million, compared to $2.5 million for the same period in 2019.
- Adjusted operating cash flow, excluding the effects of certain relief payments described below, was $0.1 million, compared to $2.5 million for the same period in 2019.

Cash and Cash Equivalents

As of Sept. 30, 2020, the Company's cash and cash equivalents totaled $183.1 million, and the outstanding principal balance on the Company's bank term loan was $23.4 million.

Third Quarter and Recent Business and Clinical Evidence Highlights

- Medicare Administrative Contractor (MAC), Palmetto GBA MolDx, issued a final expanded local coverage determination (LCD) and an accompanying billing and coding article for the company's DecisionDx-Melanoma test. The effective date is Nov. 22, 2020. Additionally, Noridian, the MAC that oversees Castle's laboratory in Arizona, issued an identical LCD to the Palmetto LCD, effective Dec. 6, 2020. The expanded LCD provides reimbursement for the significant majority of Medicare beneficiaries whose clinicians order DecisionDx-Melanoma as part of their melanoma management plan. Details on the LCD and the billing and coding article are posted to the Medicare Coverage Database on the Centers for Medicare & Medicaid Services (CMS) website.
- The Company launched its DecisionDx-SCC test, and it was made commercially available on Aug. 31, 2020. DecisionDx-SCC is a 40-gene expression profile test that uses an individual patient's tumor biology to predict individual risk of squamous cell carcinoma metastasis for patients with one or more risk factors. The test result, in which patients are stratified into a Class 1, 2A or 2B risk category, is designed to predict individual metastatic risk to inform risk-appropriate management. The Company has four peer-reviewed publications to date, demonstrating that DecisionDx-SCC is an independent predictor of metastatic risk and that integrating DecisionDx-SCC with current prognostic methods can add positive predictive value to clinician decisions regarding staging and management.
- The Company launched its DecisionDx DiffDx-Melanoma test, and it was made commercially available on Nov. 2, 2020. DecisionDx DiffDx-Melanoma is designed to aid dermatopathologists in characterizing difficult-to-diagnose melanocytic lesions. In the third quarter of 2020, in preparation for the commercial launch, the Company hired and trained a dedicated DiffDx-Melanoma commercial team, which includes outside sales representatives, medical sales liaisons and internal sales staff.
- Data from a systematic review and meta-analysis of the DecisionDx-Melanoma test was published, in print, in the September 2020 issue of the *Journal of the American Academy of Dermatology (JAAD).* Under multi-variate analysis, the DecisionDx-Melanoma test was shown to be independent from other clinical factors (age, Breslow tumor thickness, ulceration and node status) and improve upon risk assessment performed with staging factors alone. Under the Strength of Recommendation Taxonomy (SORT) system, a systematic review and meta-analysis provides for the highest level of evidence for a prognostic biomarker (Level 1 evidence). The SORT system is used by the American Academy of Dermatology and other organizations to evaluate the quality, quantity and consistency of evidence supporting tests, such as DecisionDx-Melanoma. For details, see the Company's news release from April 1, 2020.
- The publication of a retrospective study, titled "Integrating the melanoma 31-gene expression profile test to surgical oncology practice within national guideline and staging recommendations," showing that DecisionDx-Melanoma impacted management decisions for patients diagnosed with American Joint Committee on Cancer (AJCC) 7th edition stage I – III melanoma, appeared in *Future Oncology*. Study authors developed a recommended melanoma patient care algorithm that incorporates DecisionDx-Melanoma to help inform frequency and duration of follow-up visits, blood work and surveillance imaging in line with predicted metastatic risk. Patients' DecisionDx-Melanoma test result was found to have an impact on the number and duration of follow-up and surveillance visits, and patients assessed as having a high risk of metastasis (designated by a DecisionDx-Melanoma Class 2 test result) received more intensive management than patients assessed as having a low risk (designated by a DecisionDx-Melanoma Class 1 test result). Clinicians using the test were shown to adjust patient management in a risk-appropriate direction, within recommendations of national guidelines.

Conference Call and Webcast Details

Castle Biosciences will hold a conference call on Monday, Nov. 9, 2020, at 4:30 p.m. Eastern time to discuss its third quarter 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/77jh5cib 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 Nov. 30, 2020.

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 3586364.

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 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 (DecisionD®-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 expected commercial availability of our pipeline products, the impact of our tests, including DecisionDx-Melanoma, DecisionDx-SCC and DecisionDx DiffDx-Melanoma, on patient treatment plans, expectations regarding reopening of dermatology practices or rescheduled patient visits, 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 and our ability to maintain compliance with the covenants in our debt facility, the timing and amount of revenue we are able to recognize in a given fiscal period, unexpected delays in planned launch of our pipeline products, the level and availability of reimbursement for our products, our ability to manage our anticipated growth and the risks set forth in our Annual Report on Form 10-K for the year ended December 31, 2019, 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, 2020.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
NET REVENUES	$ 15,217	$ 14,774	$ 45,350	$ 34,230
COST OF SALES	2,475	1,708	7,012	5,299
Gross margin	12,742	13,066	38,338	28,931
OPERATING EXPENSES AND OTHER OPERATING LOSS				
Research and development	3,058	1,515	8,675	4,226
Selling, general and administrative	11,703	7,122	33,173	19,990
Other operating loss[1]	1,882	—	—	—
Total operating expenses	16,643	8,637	41,848	24,216
Operating (loss) income	(3,901)	4,429	(3,510)	4,715
Interest income	18	6	354	32
Interest expense	(706)	(1,088)	(2,239)	(3,805)
Gain on extinguishment of debt	—	5,213	—	5,213
Other expense, net	—	(2,711)	—	(2,933)
(Loss) income before income taxes	(4,589)	5,849	(5,395)	3,222
Income tax expense	—	—	—	—
Net (loss) income and comprehensive (loss) income	(4,589)	5,849	(5,395)	3,222
Convertible preferred stock cumulative dividends	—	289	—	2,156

Accretion of redeemable convertible preferred stock to redemption value	—	17	—	130
Net (loss) income and comprehensive (loss) income attributable to common stockholders	$ (4,589)	$ 5,543	$ (5,395)	$ 936
(Loss) earnings per share attributable to common stockholders:				
Basic	$ (0.23)	$ 0.43	$ (0.29)	$ 0.17
Diluted	$ (0.23)	$ 0.05	$ (0.29)	$ (0.67)
Weighted-average shares outstanding:				
Basic	19,936	12,758	18,290	5,649
Diluted	19,936	14,302	18,290	5,747

[1] For the three months ended September 30, 2020, reflects the reversal of income that was originally recognized during the three months ended June 30, 2020 associated with relief funds we received from the U.S. Department of Health and Human Services (HHS). We reversed this income due to a change in HHS requirements regarding application of the relief funds to lost revenues, which resulted in us concluding that it is no longer reasonably assured that we will be able to keep the funds.

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

	September 30, 2020	December 31, 2019
	(unaudited)	
ASSETS		
Current Assets		
Cash and cash equivalents	$ 183,050	$ 98,845
Accounts receivable, net	12,618	14,648
Inventory	1,679	1,237
Prepaid expenses and other current assets	3,718	1,951
Total current assets	201,065	116,681
Long-term accounts receivable, net	1,045	870
Property and equipment, net	6,646	2,060
Other assets – long-term	1,638	135
Total assets	$ 210,394	$ 119,746
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable	$ 2,101	$ 1,865
Accrued compensation	6,354	5,779
Medicare advance payment	8,350	—
Other accrued liabilities	3,435	1,812
Current portion of long-term debt	10,000	5,833
Total current liabilities	30,240	15,289
Long-term debt	12,455	19,289
Deferred rent liability and other	1,140	55
Total liabilities	43,835	34,633
Stockholders' Equity		
Common stock	20	17
Additional paid-in capital	224,146	137,308
Accumulated deficit	(57,607)	(52,212)
Total stockholders' equity	166,559	85,113
Total liabilities and stockholders' equity	$ 210,394	$ 119,746

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

	Nine Months Ended September 30,

	2020	2019
OPERATING ACTIVITIES		
Net (loss) income	$ (5,395)	$ 3,222
Adjustments to reconcile net (loss) income to net cash provided by operating activities:		
Depreciation	312	254
Stock compensation expense	5,348	536
Amortization of intangibles	—	4
Amortization of debt discounts and issuance costs	666	1,691
Other non-cash interest	—	442
Gain on extinguishment of debt	—	(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	3	—
Change in operating assets and liabilities:		
Accounts receivable	1,855	801
Prepaid expenses and other current assets	(1,767)	(1,522)
Inventory	(442)	61
Other assets	(1,503)	(20)
Accounts payable	211	(47)
Accrued compensation	575	(895)
Medicare advance payment	8,350	—
Other accrued liabilities	1,709	263
Deferred rent liability and other	373	12
Net cash provided by operating activities	10,295	2,522
INVESTING ACTIVITIES		
Purchases of property and equipment	(4,162)	(590)
Proceeds from sale of property and equipment	2	—
Net cash used in investing activities	(4,160)	(590)
FINANCING ACTIVITIES		
Proceeds from public offerings of common stock, net of underwriting discounts, commissions and offering costs	79,504	65,935
Proceeds from issuance of preferred stock and preferred stock warrants (including exercised 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	(3,333)	—
Repayments on line of credit	—	(1,791)
Proceeds from exercise of common stock options	692	1,164
Proceeds from contributions to the employee stock purchase plan	1,207	—
Net cash provided by financing activities	78,070	88,064
NET CHANGE IN CASH AND CASH EQUIVALENTS	84,205	89,996
Beginning of period	98,845	4,479
End of period	$ 183,050	$ 94,475

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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
(in thousands)				
Adjusted operating cash flow				
Adjusted operating cash flow (Non-GAAP)	$ (2,955)	$ 752	$ 63	$ 2,522
Receipt of Medicare advance payment[1]	—	—	8,350	—
Receipt of HHS provider relief funds[2]	—	—	1,882	—
Net cash provided by operating activities (GAAP)	$ (2,955)	$ 752	$ 10,295	$ 2,522

[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] In April 2020, we received a payment of $1.9 million in relief funds automatically allocated to Medicare providers under the Coronavirus Aid, Relief and Economic Security Act (CARES Act) from HHS. During the three months ended September 30, 2020, due to a change in HHS requirements regarding application of the relief funds to lost revenues, we concluded that it is no longer reasonably assured that we will be able to keep the funds. As of September 30, 2020, the relief funds are recorded as a liability on our balance sheet.

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Investor and Media Contact:
Camilla Zuckero
+1 832-835-5158
czuckero@castlebiosciences.com

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