



NEWS RELEASE

Castle Biosciences Announces Fourth Quarter and Full-Year 2019 Results

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Q4 2019 recognized revenues of \$17.6 million, compared to \$11.4 million in Q4 2018

Q4 2019 adjusted revenues of \$17.6 million, compared to \$6.2 million in Q4 2018

Full-year 2019 revenues of \$51.9 million, compared to \$22.8 million in 2018

Full-year 2019 gross margin was 86%

2020 revenue guidance of \$61-64 million

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

FRIENDSWOOD, Texas--(BUSINESS WIRE)-- 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 December 31, 2019.

"The Castle Biosciences' team delivered very strong results in 2019, with growth in test report volume and revenue, continued evidence development for DecisionDx®-Melanoma and DecisionDx®-UM tests and advancement of our pipeline products," said Derek Maetzold, president and chief executive officer of Castle Biosciences. "Our team also delivered on two commercial expansions, with all 32 outside sales territories filled as of December 2019, establishing a solid base for execution of our 2020 plan.

"We presented data on our late-stage pipeline test, DecisionDx®-SCC, for use in patients diagnosed with high-risk cutaneous squamous cell carcinoma (SCC), as defined by the National Comprehensive Cancer Network (NCCN). The data demonstrated the ability of the test to stratify patients presenting as high-risk into those who are truly high-

risk patients and those who are lower-risk patients. DecisionDx-SCC is designed to aid physicians in the development of appropriate, risk-aligned treatment plans. Our DecisionDx-SCC test remains on track for expected commercial launch in the second half of 2020.

“Additionally, development of our third skin cancer product, for use in patients with a suspicious pigmented lesion, remains on track for expected commercial launch in the second half of 2020. We estimate that combined, our three skin cancer products, DecisionDx-Melanoma, DecisionDx-SCC and our test for suspicious pigmented lesions, will have a total addressable U.S. market of approximately \$2.0 billion.”

Fourth Quarter Ended December 31, 2019, Financial Highlights

- Revenue was \$17.6 million in the fourth quarter of 2019, compared to \$11.4 million in the fourth quarter of 2018.
- Adjusted revenue was \$17.6 million in the fourth quarter of 2019, compared to \$6.2 million in the fourth quarter of 2018.
- Delivered 4,480 DecisionDx-Melanoma test reports in the fourth quarter of 2019, which represents 37% growth compared to the 3,270 reports delivered during the fourth quarter of 2018.
- Delivered 434 DecisionDx-UM test reports in the fourth quarter of 2019, which represents 13% growth compared to 385 reports during the fourth quarter of 2018.
- Gross margin in the fourth quarter of 2019 was 89%.
- Operating cash flow was \$4.5 million in the fourth quarter of 2019, compared to \$(3.2) million in the fourth quarter of 2018.

Twelve Months Ended December 31, 2019, Financial Highlights

- Revenue was \$51.9 million for the full year 2019, compared to \$22.8 million in 2018.
- Delivered 15,529 DecisionDx-Melanoma test reports for the full year 2019, compared to 12,032 reports during the full year 2018, representing growth of 29%. In 2019, new ordering clinicians for DecisionDx-Melanoma increased 24% compared to 2018. Additionally, total ordering clinicians in 2019 for DecisionDx-Melanoma increased 32% to 3,927, year-over-year.
- Delivered 1,526 DecisionDx-UM test reports for the full year 2019, compared to 1,413 reports during the full year 2018, representing growth of 8%.
- Gross margin for the full year 2019 was 86%.
- Operating cash flow was \$7.0 million for the full year 2019, compared to \$(12.3) million in 2018.

Cash and Cash Equivalents

As of December 31, 2019, the Company's cash and cash equivalents totaled \$99 million, and the outstanding

principal balance on the Company's bank term loan was \$26.7 million.

2020 Revenue Guidance

Castle Biosciences anticipates generating \$61-64 million in revenue in 2020.

Supplemental Revenue Information

Affecting the year-over-year comparability of our revenues were (a) the issuance of the Medicare Local Coverage Determination (LCD) for our DecisionDx-Melanoma test, effective December 3, 2018, and (b) confirmation of the Medicare Contractor rate for DecisionDx-Melanoma. As a result of timing of these two elements, all 2018 Medicare claims covered under the LCD were recognized as revenue in the fourth quarter of 2018. Medicare revenues for DecisionDx-Melanoma associated with test reports delivered in the first three quarters of 2018, but not recorded until the fourth quarter of 2018, were \$5.2 million. Also, included in revenues for the quarters ended December 31, 2019 and 2018, were positive (negative) revenue adjustments related to tests delivered in prior periods of \$4.3 million and \$(1.2) million, respectively. For the twelve months ended December 31, 2019, and 2018, these amounts totaled \$2.5 million and \$0.3 million, respectively.

Fourth Quarter Business and Clinical Evidence Updates

- The Company more than doubled the number of commercial and medical affairs personnel between December 2018 and December 2019. The most recent expansion occurred in December 2019, with an increase in the number of outside sales territories to 32 from 23, along with commensurate increases in other commercial and medical affairs support roles. The Company previously expanded the number of outside sales territories to 23 from 14 in February 2019.
- Results from a study designed to perform a systematic review of the literature and establish the level of evidence for the Company's DecisionDx-Melanoma gene expression profile test were published in the December 2019 issue of the American Journal of Clinical Dermatology. The results suggest that the DecisionDx-Melanoma test achieves a higher level of evidence than required by major organizations that publish guidelines on melanoma management. The evaluation of seven development and validation studies led the authors to classify DecisionDx-Melanoma as level I/II, 1-3B and IIA according to the American Joint Committee on Cancer (AJCC), National Comprehensive Cancer Network (NCCN) and American Academy of Dermatology (AAD) criteria, respectively, which are higher than the official unrated status conferred by the AJCC and NCCN and the II/IIIC rating designated by the AAD in the latest version of their melanoma guidelines.
- The NCCN Guidelines for Cutaneous Melanoma were updated in the fourth quarter, with a positive shift in the inclusion language indicating that the DecisionDx-Melanoma test may provide information that is an adjunct to AJCC staging, with a category 2A level of evidence recommendation. This level of evidence is consistent with

the systematic review study published in December 2019 (see American Journal of Clinical Dermatology publication noted earlier).

- The Company received notification that the American Medical Association's (AMA) Current Procedural Terminology (CPT) Editorial Panel accepted Castle's application for a Category I Multianalyte Assays with Algorithmic Analyses (MAAA) CPT code for its DecisionDx-Melanoma test. The CPT Editorial Panel is an independent group of expert volunteers representing various sectors of the health care industry. Its role is to ensure that code changes undergo evidence-based review and meet specific criteria. The code will be effective on January 1, 2021. With this acceptance, both of the Company's proprietary MAAA tests, DecisionDx-UM and DecisionDx-Melanoma, have met the criteria required for a Category I MAAA CPT code.
- Data from a second, multi-center, prospectively tested patient cohort study of 1,166 patients supporting clinical use of the DecisionDx-Melanoma test to inform discussions and recommendations regarding sentinel lymph node biopsy (SLNB), as well as data from a separate multi-center prospective outcomes study were presented during the 16th International Congress of the Society for Melanoma Research.

In the expanded, multi-center prospectively tested patient cohort study:

• In SLNB-assessed patients 65 years of age or older with T1-T2 tumors and a Class 1A test result, SLN positivity was 2.7%, significantly less than patients with a Class 1B-2A ($p < 0.01$) or Class 2B result ($p < 0.0001$), and below the 5% threshold at which guidelines do not recommend the procedure.

In the multi-center prospective outcomes study:

• In a prospective cohort with median follow-up of 3.2 years for patients without an event, Class 1A patients with T1-T2 melanoma, at three years, had overall survival of 99.4%, distant metastasis-free survival of 98.7% and recurrence-free survival of 96.6%, adding further support that this population can safely avoid the SLNB surgical procedure.

- DecisionDx-SCC, the Company's late stage pipeline product expected to be commercially available in the second half of 2020, is designed to predict a low risk of metastasis in patients with cutaneous squamous cell carcinoma (SCC), who are identified as high risk by traditional clinicopathologic staging criteria. Results of the clinical validation study (n=321) for DecisionDx-SCC were presented in October 2019 at the American Society for Dermatologic Surgery (ASDS) Annual Meeting. The development goal for DecisionDx-SCC was to enable a clinician to consider de-escalating treatment plans in patients with one or more high-risk clinical or pathologic features who are at low biological risk of metastasis, and with the remaining patients having a significantly higher risk of metastasis, enabling more accurate implementation of risk directed treatment plans.

Recent Developments

- In January 2020, the Company presented data supporting a framework for integration of DecisionDx-SCC into risk-appropriate management of high-risk cutaneous SCC patients (as defined by NCCN) at the 2020 Winter

Clinical Dermatology Conference. The study found that integration of DecisionDx-SCC for NCCN-defined high-risk cutaneous SCC patients with T staging identified a group of patients (Class 1, T1-T2) with a 7.5% rate of metastasis, which approaches that of the general cutaneous SCC patient population. A low intensity management strategy, within the broad NCCN high-risk guidelines, could spare this patient group unnecessary adjuvant procedures and potential adverse effects.

- Earlier this March, the first U.S. Patent related to the Company's DecisionDx-Melanoma test was issued (Patent No. 10,577,660) by the United States Patent and Trademark Office (USPTO). This patent brings the total number of issued or allowed patents related to DecisionDx-Melanoma to 10 and covers methods of treating cutaneous melanoma in patients having high-risk cutaneous melanoma tumors.

Conference Call and Webcast Details

Castle Biosciences will hold a conference call on Tuesday, March 10, 2020, at 4:30 p.m. Eastern time to discuss its fourth quarter and full-year 2019 results and provide a corporate update.

A live webcast of the conference call can be accessed here: <https://edge.media-server.com/mmc/p/z5thjfrt> 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 April 1, 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 5836318.

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 Revenue, which is a non-GAAP financial measure and is not calculated in accordance with generally acceptance accounting principles in the United States (GAAP). This non-GAAP financial measure reflects adjustments to total revenue associated with certain test reports delivered in one reporting period that were not recognizable until a later reporting period because all the criteria for revenue recognition were not met under GAAP. Specifically, we did not have a Medicare LCD in place for our DecisionDx-Melanoma test until the fourth quarter of 2018. When issued, the LCD also provided coverage for payment of claims beginning in February 2018. Therefore, all the revenue covered by the LCD associated with tests delivered in the first through third quarters of 2018 were not recognized in our reported GAAP revenue until the fourth quarter of 2018. For the fourth quarter of 2018, Adjusted Revenue excludes revenue that was recognized during such quarter that relate to test reports covered by the LCD that were delivered in the first through third quarters of 2018. Since the LCD was in

effect for all of 2019, Adjusted Revenue for the fourth quarter of 2019 is the same as revenue calculated in accordance with GAAP.

We use Adjusted Revenue internally because we believe this metric provides useful supplemental information in understanding changes in our year-over-year financial performance by reflecting DecisionDx-Melanoma Medicare LCD revenue in the periods the test reports were delivered. 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 revenue reported in accordance with GAAP and should be considered in conjunction with our financial information presented on a 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 release.

About Castle Biosciences, Inc.

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®-CMSeq; www.SkinMelanoma.com) and uveal melanoma (DecisionDx®-UM, DecisionDx®-PRAME and DecisionDx®-UMSeq; www.MyUvealMelanoma.com), with products in development for other underserved cancers, the two most advanced of which are focused on patients with cutaneous squamous cell carcinoma, and patients who have a difficult-to-diagnose pigmented lesion. Castle Biosciences is based in Friendswood, Texas (Houston), and has laboratory operations in Phoenix, Arizona. For more information, visit www.CastleBiosciences.com.

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 expected commercial availability of our pipeline products, estimated total addressable market attributable to these pipeline products, our plans for commercial expansion, including anticipated number of sales territories and related increased hiring activity, the impact of our tests, including DecisionDx-Melanoma, on patient treatment plans, our revenue expectations for 2020, 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 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 final prospectus filed with the SEC on July 26, 2019 relating to our Registration Statements on Form S-1 (File Nos. 333-232369 and 333-232796) and our Quarterly Report on Form 10-Q for the quarter ended September 30, 2019, filed with the SEC on November 12, 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.

CASTLE BIOSCIENCES, INC.
CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)

(in thousands, except per share data)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2019	2018	2019	2018
	(unaudited)		(unaudited)	
NET REVENUES	\$ 17,635	\$ 11,436	\$51,865	\$22,786
COST OF SALES	2,011	1,366	7,310	5,297
Gross margin	15,624	10,070	44,555	17,489
OPERATING EXPENSES				
Research and development	3,159	1,138	7,385	4,854
Selling, general and administrative	9,852	4,165	29,842	16,471
Total operating expenses	13,011	5,303	37,227	21,325

Operating income (loss)	2,613	4,767	7,328	(3,836)
Interest income	280	3	312	24
Interest expense	(766)	(650)	(4,571)	(2,274)
Gain on extinguishment of debt	—	—	5,213	—
Other expense, net	—	(243)	(2,933)	(272)
Income (loss) before income taxes	2,127	3,877	5,349	(6,358)
Income tax expense	72	9	72	9
Net income (loss) and comprehensive income (loss)	2,055	3,868	5,277	(6,367)
Convertible preferred stock cumulative dividends	—	949	2,156	3,577
Accretion of redeemable convertible preferred stock to redemption value	—	57	130	219
Net income (loss) and comprehensive income (loss) attributable to common stockholders	\$ 2,055	\$ 2,862	\$2,991	\$(10,163)
Earnings (loss) per share attributable to common stockholders:				
Basic	\$ 0.12	\$ 1.49	\$0.35	\$(5.33)
Diluted	\$ 0.11	\$ 0.38	\$(0.21)	\$(5.33)
Weighted-average shares outstanding:				
Basic	17,295	1,916	8,584	1,906
Diluted	18,600	10,301	8,658	1,906

CASTLE BIOSCIENCES, INC.

CONDENSED BALANCE SHEETS

(in thousands)

December 31,

2019 2018

ASSETS

Current Assets

Cash and cash equivalents	\$ 98,845	\$ 4,479
Accounts receivable, net	14,648	12,090
Inventory	1,237	882
Prepaid expenses and other current assets	1,951	675
Total current assets	116,681	18,126
Long-term accounts receivable, net	870	2,532
Property and equipment, net	2,060	1,529
Intangible assets, net	—	4
Other assets – long-term	135	214
Total assets	\$ 119,746	\$ 22,405

LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)

Current Liabilities

Accounts payable	\$ 1,865	\$ 1,451
Accrued compensation	5,779	4,571
Other accrued liabilities	1,812	715
Current portion of long-term debt	5,833	—
Total current liabilities	15,289	6,737
Long-term debt	19,289	24,500
Preferred stock warrant liability	—	1,194
Deferred rent liability	55	44
Total liabilities	34,633	32,475

Convertible Preferred Stock

Convertible preferred stock Series C	—	1,501
Redeemable convertible preferred stock Series A, B, D, E-1, E-2, E-2A, E-3 and F	—	44,995

Stockholders' Equity (Deficit)

Common stock	17	2
Additional paid-in capital	137,308	921
Accumulated deficit	(52,212)	(57,489)
Total stockholders' equity (deficit)	85,113	(56,566)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	\$ 119,746	\$ 22,405

CASTLE BIOSCIENCES, INC.

CONDENSED STATEMENTS OF CASH FLOWS

(in thousands)

	Twelve Months Ended December 31,	
	2019	2018
OPERATING ACTIVITIES		
Net income (loss)	\$ 5,277	\$ (6,367)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation	354	287
Stock compensation expense	1,249	294
Amortization of intangibles	4	36
Amortization of debt discounts and issuance costs	1,925	566
Other non-cash interest	442	—
Gain on extinguishment of debt	(5,213)	—
Change in fair value of preferred stock warrant liability	619	272
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	—	(24)
Change in operating assets and liabilities:		
Accounts receivable	(896)	(8,408)

Prepaid expenses and other current assets	(1,276)	(160)
Inventory	(355)	(578)
Other assets	(85)	14
Accounts payable	557	197
Accrued compensation	1,208	1,347
Other accrued liabilities	879	201
Deferred rent liability	12	28
Net cash provided by (used in) operating activities	7,015	(12,295)
INVESTING ACTIVITIES		
Purchases of property and equipment	(937)	(277)
Net cash used in investing activities	(937)	(277)
FINANCING ACTIVITIES		
Proceeds from initial public offering of common stock, net of underwriting discounts, commissions and issuance costs	65,931	—
Proceeds from issuance of preferred stock and preferred stock warrants (including exercised warrants)	49	10,383
Proceeds from issuance of term debt and preferred stock warrants, net of issuance costs	—	4,418
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	—
Proceeds from line of credit	—	1,000
Repayments on line of credit	(1,791)	—
Proceeds from exercise of common stock options	1,174	38
Proceeds from contributions to the employee stock purchase plan	218	—
Net cash provided by financing activities	88,288	15,839
NET CHANGE IN CASH AND CASH EQUIVALENTS		
Beginning of period	4,479	1,212
End of period	\$ 98,845	\$ 4,479

CASTLE BIOSCIENCES, INC.

Reconciliation of Non-GAAP Financial Measures (UNAUDITED)

The table below presents the reconciliation of adjusted revenue, 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,	
	2019	2018
(in thousands)		
Adjusted Revenues		
Adjusted Revenues (Non-GAAP)	\$ 17,635	\$ 6,245
DecisionDx-Melanoma Medicare revenue associated with test reports delivered prior to 4Q18 not recognizable until 4Q18	—	5,191
Net Revenues (GAAP)	\$ 17,635	\$ 11,436

View source version on [businesswire.com](https://www.businesswire.com/news/home/20200310005837/en/): <https://www.businesswire.com/news/home/20200310005837/en/>

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