UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K
CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 11, 2019

Castle Biosciences, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-38984**	**77-0701774**
(state or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

820 S. Friendswood Drive, Suite 201 **Friendswood, Texas**	**77546**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (866) 788-9007

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value per share	**CSTL**	**The Nasdaq Global Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b–2 of the Securities Exchange Act of 1934 (§ 240.12b–2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On November 11, 2019, Castle Biosciences, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2019. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

The information contained or incorporated in this report, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference into any filing under the Exchange Act or the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press release issued November 11, 2019.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CASTLE BIOSCIENCES, INC.

By: /s/ Frank Stokes

Frank Stokes

Chief Financial Officer

Date: November 12, 2019

CASTLE BIOSCIENCES

Castle Biosciences Reports Third Quarter 2019 Results

Q3 2019 DecisionDx-Melanoma test report volume increased 32% compared to Q3 2018
Q3 2019 recognized revenues increased to $14.8 million, up from $3.7 million in Q3 2018
Q3 2019 gross margin increased to 88%, up from 64% in Q3 2018
December 2019 salesforce expansion
Presented clinical validation data for DecisionDx-SCC
Conference call and webcast today at 4:30 p.m. ET

FRIENDSWOOD, TEXAS- November 11, 2019--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 September 30, 2019.

“We are pleased with our strong third quarter performance, driven by solid growth in our DecisionDx®-Melanoma test report volume, which is a result of our investment in evidence development and scaling our commercial team in the first quarter of 2019,” said Derek Maetzold, president and chief executive officer of Castle Biosciences. "Based upon our results, we have decided to execute our commercial expansion plans in December 2019.

“We recently presented the clinical validation study data for our DecisionDx-SCC test for use in patients diagnosed with high risk cutaneous squamous cell carcinoma, which we expect to launch in the second half of 2020. Additionally, we continue to progress our third skin cancer product for use in patients with a suspicious pigmented lesion, which is also on track for anticipated commercial availability in the second half of 2020. We believe these two late stage pipeline products will increase our estimated total addressable U.S. market by more than $1.4 billion, for an estimated total addressable U.S. market of $2.0 billion for current and pipeline products.”

Third Quarter Ended September 30, 2019, Financial Highlights

- Revenues were $14.8 million, an increase of $11.1 million from Q3 2018.
- Delivered 4,126 DecisionDx®-Melanoma test reports in the 2019 third quarter, compared to 3,136 reports during the third quarter of 2018, representing growth of 32%.
- Delivered 356 DecisionDx®-UM test reports in the 2019 third quarter, compared to 324 reports during the third quarter of 2018, representing growth of 10%.
- Gross margin was $13.1 million, or 88%.
- Operating cash flows were $0.8 million in Q3 2019, compared to $(1.9) million in Q3 2018.

Nine Months Ended September 30, 2019, Financial Highlights

- Revenues were $34.2 million, an increase of $22.9 million over the same period in 2018.
- Delivered 12,141 DecisionDx-Melanoma and DecisionDx-UM proprietary test reports, an increase of 24% over the same period in 2018, with DecisionDx-Melanoma increasing 26%.

- Gross margin was $28.9 million, or 85%.
- Operating cash flows were $2.5 million, compared to $(9.1) million for the same period in 2018.

Cash and Cash Equivalents

As of September 30, 2019, the Company's cash and cash equivalents was $94.5 million, and the outstanding principal balance on our bank term loan was $26.7 million.

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 three and nine months ended September 30, 2018, but not recorded until the fourth quarter of 2018, were $2.2 million and $5.2 million, respectively. Also, included in revenues for the quarter ended September 30, 2019, and 2018, were positive (negative) revenue adjustments related to tests delivered in prior periods of $3.2 million and $(1.2) million, respectively. For the nine months ended September 30, 2019, and 2018, these amounts totaled $2.4 million and $0.6 million, respectively.

Third Quarter Business and Clinical Evidence Updates

- The Company expanded the number of outside sales territories from 14 to 23 in the first quarter of 2019, with commensurate increases in other commercial and medical affairs support roles. Subsequently, new ordering clinicians for DecisionDx-Melanoma grew 26% in the third quarter, compared to the same period in 2018. For comparison purposes, third quarter growth in new ordering clinicians in 2018 was 5%, compared to the same period in 2017. As a result, the Company has decided to execute its commercial expansion plans in December 2019, which is expected to include the addition of nine new outside sales territories and commensurate increases in commercial and medical affairs support roles.
- A multicenter study establishing an evidence-based population to guide appropriate use of the DecisionDx-Melanoma test in patients with thinner (1.0 mm or less) melanoma tumors was published in the peer-reviewed journal *SKIN: The Journal of Cutaneous Medicine.* The results established a minimum Breslow thickness of 0.3 mm as an appropriate population to use DecisionDx-Melanoma to guide decisions on treatment plan decisions for follow-up and surveillance for cutaneous melanoma patients. An earlier publication (February 2019) established appropriate use criteria for the treatment plan decision to guide sentinel lymph node biopsy (SNLB) surgical procedures in patients diagnosed with a melanoma ≤2.0mm thick. Together, these two appropriate use criteria cover more than 90% of all melanoma patients currently tested.

- The Company closed the initial public offering of 4,600,000 shares of its common stock, which included 600,000 shares sold pursuant to the exercise in full by the underwriters of their option to purchase additional shares, at a price to the public of $16.00 per share. Including the option exercise, the gross proceeds to the Company from the offering, before deducting the underwriting discounts and commissions and offering expenses, were $73.6 million.
- The Company was added as a member of the U.S. small-cap Russell 2000® Index. Membership in the Russell 2000® Index, which remains in place for one year, is based on membership in the broad-market Russell 3000® Index. The stock also was automatically added to the appropriate growth and value indexes.

Recent Developments

- An expert panel consensus statement that includes appropriate use criteria for DecisionDx-Melanoma in patients with cutaneous melanoma was published in the peer-reviewed journal *SKIN: The Journal of Cutaneous Medicine*. Using a modified Delphi technique, the panel established an evidence-based appropriate use framework to integrate the DecisionDx-Melanoma test into the management of patients with cutaneous melanoma. The appropriate use recommendations cover more than 90% of all patients currently tested.
- One of the two appropriate uses of the DecisionDx-Melanoma test is the ability to guide or rule out a SLNB surgical procedure in patients with a melanoma ≤2.0mm thick. The Company published data from a prospective, multi-center, consecutively tested population of 1,421 patients in February 2019, that demonstrated that a Class 1A test result identified a group of patients with melanomas ≤2.0mm thick, in which the likelihood of a positive sentinel lymph node (SLN) was ≤5%; the National Comprehensive Cancer Network (NCCN) threshold for offering a SLNB surgical procedure. Within this ≤2.0mm group, an important question is performance of DecisionDx-Melanoma in “thin” melanomas, which are defined as a melanoma ≤1.0mm deep.

  In October, the Company presented data on a new prospective, multi-center, consecutively tested cohort of 1,166 patients at the International Congress on Cancer Metastasis. The study combined patients with melanoma with those of the study published in February 2019, for a total number of patients with melanomas ≤1.0mm thick of 1,058. Within this group, the SLN positivity rate for patients with a Class 1A test result of any age was 3.2%, for patients ≥65 years of age, the rate was 0.9% and for those ≥65 years of age who underwent a SLNB procedure, the SLN positivity rate was 1.0%. These data support the use of a DecisionDx-Melanoma Class 1A test result in patients with a melanoma ≤1.0mm deep to identify patients who are at low risk for a positive SLN and can avoid a SLNB surgical procedure. SLNB surgery has an average reimbursed cost of $20,000 to $24,000; therefore, this could represent a significant potential healthcare savings, in addition to enabling patients to avoid a surgical procedure with an 11% complication rate.

- Nomograms are a clinical tool that enable clinicians to combine independent risk factors to estimate an individual cancer patient's likelihood of recurrence or metastasis. In October, the Cutaneous Oncology Research Consortium (CORC) presented a nomogram that was developed from data on a prospectively tested cohort of 1,124 patients, 685 of which had ≥1 year of recurrence-free follow-up or a recurrence event (median follow-up =3.0 years) and were included in development of the nomogram. The nomogram demonstrated that the combination of DecisionDx-Melanoma test results with Breslow's thickness and ulceration, commonly referred to as T-stage, improved prediction of patients' risk of melanoma recurrence compared to clinicopathologic features alone. This nomogram was independently validated using the Company's archival study of 901 patients.
- 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 recently presented at the American Society for Dermatologic Surgery (ASDS) Annual Meeting. The development goal for DecisionDx-SCC was to enable a clinician to de-escalate treatment plans in patients with one or more high risk clinical or pathologic features who are at low biological risk of metastasis. Importantly, 93% of patients in the validation cohort had one or more high risk features. The validation data showed that approximately 60% of high-risk patients were identified as low risk with a Negative Predictive Value (NPV) of 91.1%. Conversely, the highest risk of the remaining patients had a Positive Predictive Value (PPV) of 60%, compared to 35.3% for the Brigham and Women's criteria, 20.9% for the American Joint Committee on Cancer and 16.7% for NCCN risk criteria.
- Data from a multicenter, prospective study demonstrating that DecisionDx-UM test results significantly impacted treatment plan recommendations for patients with uveal melanoma was presented at the American Academy of Ophthalmology 2019 Annual Meeting. The CLEAR II study (Clinical Application of DecisionDx-UM Gene Expression Assay Results) was designed to prospectively evaluate metastatic surveillance regimens for patients with uveal melanoma, who were tested with the DecisionDx-UM gene expression profile (GEP) test as part of their diagnostic work-up. The study met the primary endpoints demonstrating a clinically and statistically relevant reduction in treatment plans for patients with a low risk Class 1 test result, compared to a Class 2 test result, with 95% of Class 2 patients being referred to medical oncology.
- The Company received notification that the American Medical Association (AMA)'s Current Procedural Terminology (CPT) Editorial Panel accepted its 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. Their role is to ensure that code changes undergo evidence-based review and meet specific criteria. The code will be effective on January 1, 2021.

Conference Call and Webcast Details

Castle Biosciences will hold a conference call on Monday, November 11, 2019, at 4:30 p.m. Eastern time to discuss its third quarter 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/pivux23i 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 December 2, 2019.

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 4476877.

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

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 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 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 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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
NET REVENUES	$ 14,774,891	$ 3,711,759	$ 34,230,447	$ 11,349,705
COST OF SALES	1,708,722	1,350,799	5,299,464	3,930,621
Gross margin	13,066,169	2,360,960	28,930,983	7,419,084
OPERATING EXPENSES				
Research and development	1,514,966	1,294,301	4,226,054	3,716,188
Selling, general and administrative	7,121,982	3,918,387	19,989,531	12,305,933
Total operating expenses	8,636,948	5,212,688	24,215,585	16,022,121
Operating income (loss)	4,429,221	(2,851,728)	4,715,398	(8,603,037)
Interest income	5,190	13,266	31,508	20,889
Interest expense	(1,088,130)	(568,774)	(3,805,112)	(1,623,842)
Gain on extinguishment of debt	5,213,431	—	5,213,431	—
Other expense, net	(2,710,417)	(42,796)	(2,932,992)	(29,456)
Income (loss) before income taxes	5,849,295	(3,450,032)	3,222,233	(10,235,446)
Income tax expense	—	—	—	—
Net income (loss) and comprehensive income (loss)	5,849,295	(3,450,032)	3,222,233	(10,235,446)
Convertible preferred stock cumulative dividends	288,891	949,202	2,156,358	2,627,532
Accretion of redeemable convertible preferred stock to redemption value	17,578	56,843	130,151	161,863
Net income (loss) and comprehensive income (loss) attributable to common stockholders	$ 5,542,826	$ (4,456,077)	$ 935,724	$ (13,024,841)
Earnings (loss) per share attributable to common stockholders:				
Basic	$ 0.43	$ (2.33)	$ 0.17	$ (6.85)
Diluted	$ 0.05	$ (2.33)	$ (0.67)	$ (6.85)
Weighted-average shares outstanding:				
Basic	12,757,658	1,912,429	5,648,757	1,902,314
Diluted	14,301,663	1,912,429	5,746,610	1,902,314

CASTLE BIOSCIENCES, INC.
CONDENSED BALANCE SHEETS

	September 30, 2019	December 31, 2018
	(unaudited)	
ASSETS		
Current Assets		
Cash and cash equivalents	$ 94,474,818	$ 4,478,512
Accounts receivable, net	12,369,260	12,089,719
Inventory	821,658	882,233
Prepaid expenses and other current assets	2,197,235	675,562
Total current assets	109,862,971	18,126,026
Long-term accounts receivable, net	1,451,872	2,532,011
Property and equipment, net	1,798,236	1,528,996
Intangible assets, net	—	4,167
Other assets – long-term	87,168	213,735
Total assets	$ 113,200,247	$ 22,404,935
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current Liabilities		
Accounts payable	$ 1,251,267	$ 1,450,766
Accrued compensation	3,676,164	4,571,011
Other accrued liabilities	976,977	715,244
Current portion of long-term debt	3,333,333	—
Total current liabilities	9,237,741	6,737,021
Long-term debt	21,570,372	24,499,752
Preferred stock warrant liability	—	1,193,726
Deferred rent liability	56,006	43,587
Total liabilities	30,864,119	32,474,086
Convertible Preferred Stock		
Convertible preferred stock Series C	—	1,500,994
Redeemable convertible preferred stock Series A, B, D, E-1, E-2, E-2A, E-3 and F	—	44,995,157
Stockholders' Equity (Deficit)		
Common stock	17,074	1,916
Additional paid-in capital	136,585,399	921,360
Accumulated deficit	(54,266,345)	(57,488,578)
Total stockholders' equity (deficit)	82,336,128	(56,565,302)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 113,200,247	$ 22,404,935

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

	Nine Months Ended September 30,	
	2019	**2018**
OPERATING ACTIVITIES		
Net income (loss)	$ 3,222,233	$ (10,235,446)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation	254,312	216,014
Stock compensation expense	536,713	220,732
Amortization of intangibles	4,167	27,452
Amortization of debt discounts and issuance costs	1,690,621	426,071
Other non-cash interest	442,176	—
Gain on extinguishment of debt	(5,213,431)	—
Change in fair value of preferred stock warrant liability	619,024	29,456
Change in fair value of embedded derivative	237,199	—
Change in fair value of convertible promissory note accounted for under the fair value option	2,076,768	—
Other	337	—
Change in operating assets and liabilities:		
Accounts receivable	800,598	(655,247)
Prepaid expenses and other current assets	(1,521,673)	(15,408)
Inventory	60,575	(5,671)
Other assets	(20,256)	(49,282)
Accounts payable	(46,932)	(170,890)
Accrued compensation	(894,847)	1,016,014
Other accrued liabilities	261,737	83,803
Deferred rent liability	12,419	28,022
Net cash provided by (used in) operating activities	2,521,740	(9,084,380)
INVESTING ACTIVITIES		
Purchases of property and equipment	(589,664)	(271,620)
Net cash used in investing activities	(589,664)	(271,620)
FINANCING ACTIVITIES		
Proceeds from initial public offering of common stock, net of underwriting discounts, commissions and issuance costs	65,935,428	—
Proceeds from issuance of preferred stock and preferred stock warrants (including exercised warrants)	49,017	10,382,514
Proceeds from issuance of convertible promissory notes, net of issuance costs	11,695,495	—
Proceeds from issuance of convertible promissory note and common stock warrant, net of issuance costs	9,235,744	—
Proceeds from issuance of term debt, net of issuance costs	1,776,145	—
Proceeds from line of credit	—	1,000,000
Repayments on line of credit	(1,791,145)	—
Proceeds from exercise of common stock options	1,163,546	37,696
Net cash provided by financing activities	88,064,230	11,420,210
NET CHANGE IN CASH AND CASH EQUIVALENTS	89,996,306	2,064,210
Beginning of period	4,478,512	1,212,063
End of period	$ 94,474,818	$ 3,276,273