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 4, 2026

BillionToOne, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	001-42934	81-1082020
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

1035 O'Brien Drive
Menlo Park, CA 94025
(Address of principal executive offices including zip code)

Registrant's telephone number, including area code: (650) 460-2551

(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	Name of each exchange on which registered
Class A common stock, par value $0.00001 per share	**BLLN**	**The Nasdaq Stock Market LLC**

Indicate by check mark whether the registrant is an emerging growth company 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 4, 2026, BillionToOne, Inc. (the "Company") issued a press release announcing financial results for the quarter ended September 30, 2026. A copy of the Company's press release is attached hereto as Exhibit 99.1.

The information in this Current Report on Form 8-K and the accompanying 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"), and is not to be incorporated by reference into any filing by the Company under the Securities Act of 1933, as amended or the Exchange Act, regardless of any general incorporation language contained in such filing, unless otherwise expressly stated in such filing.

Item 9.01 Financial Statements and Exhibits
(d) Exhibits.

Exhibit	Description
99.1	Press Release of BillionToOne, Inc. dated November 4, 2026
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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

BillionToOne, Inc.

Date: November 4, 2026

By: /s/ Ross Taylor

Name: Ross Taylor

Title: Chief Financial Officer

BillionToOne Reports Third Quarter 2026 Results and Raises 2026 Revenue Guidance

MENLO PARK, CA, November 4, 2026 - BillionToOne, Inc. (NASDAQ: BLLN), a next-generation molecular diagnostics company with a mission to create powerful and accurate tests that are accessible to all, today reported its financial results for the third quarter ended September 30, 2026 and raised guidance for full year 2026.

Financial Highlights:

- Total revenue of $123.0 million in the third quarter of 2026, compared to $83.5 million in the third quarter of 2025, an increase of 47%.
- Prenatal clinical testing revenue was $104.3 million in the third quarter of 2026, an increase of 41% from the third quarter of 2025.
- Oncology clinical testing revenue was $17.1 million in the third quarter of 2026, 96% higher than the $8.7 million reported in the third quarter of 2025.
- Gross profit margin was 71% in the third quarter of 2026, compared to 70% in the third quarter of 2025, a one percentage-point increase year-over-year.
- 206,000 tests delivered in the third quarter of 2026, compared to 165,000 tests delivered in the third quarter of 2025, an increase of 25%.
- Income from operations of $11.0 million in the third quarter of 2026, compared to income from operations of $9.6 million in the third quarter of 2025.
- Free cash flow, defined as cash flow from operations minus capital expenditures, was $8.6 million in the third quarter of 2026.
- Raising 2026 full year revenue guidance to be in a range of $460 million to $470 million, which represents 51% to 54% growth over 2025.
- Expects to operate the business such that it will continue to generate profitability similar to current levels, even with significant continued investments.

Recent Operating Highlights:

- Today, we announced the upcoming launch of Northstar Clear, a tissue-free MRD test for patients with all solid tumors, which will be commercially available on December 15, 2026. Its pan-cancer, blood-only design makes it available on day one for all solid tumors, and initial data in colorectal cancer will show head-to-head performance against a tumor-informed assay.
- In October 2026, we announced peer-reviewed data published in The Journal of Liquid Biopsy from the first head-to-head comparison of Northstar Response with the most widely used tumor-informed assay in patients on active treatment for advanced cancer. The two assays agreed on the direction of ctDNA change in 94% of sequential pairs (67 of 71), and in all four divergent cases clinical records supported Northstar Response's findings.
- In August 2026, we announced peer-reviewed data published in The Green Journal (Obstetrics & Gynecology) validating Unity Fetal Risk Screen as a first-line prenatal screen. The study is the first and largest prospective study of Unity Fetal Risk Screen in its intended-use population and was conducted in collaboration with nine U.S. institutions, demonstrating 94.4% sensitivity and 99.5% specificity.

"Our third quarter was another period of strong execution," said Dr. Oguzhan Atay, Co-Founder and CEO of BillionToOne. "We delivered rapid growth with continued GAAP profitability, and more clinicians are

choosing our tests in both prenatal and oncology. This quarter we also strengthened the clinical evidence behind our platform. Published data validated Unity Fetal Risk Screen as a first-line prenatal screen, and Northstar Response delivered strong results in the first head-to-head study of its kind. I am also pleased to announce that next month, we plan to launch Northstar Clear, our MRD test. Overall, we are proud of our performance so far in 2026 and believe we are still in the early chapters of what our platform can achieve."

	Three Months Ended September 30, (Unaudited)			Nine Months Ended September 30, (Unaudited)		
	2026	2025	%	2026	2025	%
Revenue ($ in millions)						
Prenatal	$ 104.3	$ 74.1	41 %	$ 295.1	$ 191.0	54 %
Oncology	$ 17.1	$ 8.7	96 %	$ 41.4	$ 15.8	162 %
Clinical trial support and other services	$ 1.6	$ 0.8	115 %	$ 4.3	$ 2.2	92 %
Total Revenue	$ 123.0	$ 83.5	47 %	$ 340.8	$ 209.1	63 %

Note: Numbers may not add due to rounding

	Three Months Ended September 30, (Unaudited)			Nine Months Ended September 30, (Unaudited)		
	2026	2025	%	2026	2025	%
Total tests accessioned	207,000	163,000	27 %	593,000	448,000	32 %
Total tests delivered	206,000	165,000	25 %	590,000	441,000	34 %
Overall ASP	$ 589	$ 501	18 %	$ 571	$ 469	22 %

Third Quarter 2026 Financial Results

Total revenue was $123.0 million in the third quarter of 2026 compared to $83.5 million in the third quarter of 2025, an increase of 47%. The increase in total revenue was driven by a 25% increase in the number of total tests delivered and an 18% increase in Overall ASP. Both prenatal and oncology delivered strong test volume growth year-over-year.

Gross profit was $87.1 million in the third quarter of 2026, compared to $58.4 million in the third quarter of 2025, representing a gross margin of 71% in the third quarter of 2026 and 70% in the third quarter of 2025. An increase in Overall ASP drove the improvement in gross profit margin compared to the third quarter of 2025. Overall cost-per-test increased slightly in the third quarter of 2026 compared to last year. The increase was driven by the faster growth of our oncology products, which have higher costs per test, and a slight increase in our prenatal cost per test, partially offset by improvements in cost-per-test for both of our oncology products.

Total operating expenses were $76.1 million in the third quarter of 2026, compared to $48.8 million in the third quarter of 2025, an increase of 56%.

Income from operations was $11.0 million in the third quarter of 2026, compared to income from operations of $9.6 million in the third quarter of 2025. Operating margin was 9% in the third quarter of 2026.

Net income in the third quarter of 2026 was $17.4 million, or $0.32 per diluted share, compared to net income of $1.5 million, or $0.10 per diluted share, in the third quarter of 2025.

Financial Outlook

BillionToOne now expects full year 2026 total revenue of $460.0 million to $470.0 million, representing growth of 51% to 54% compared to full year 2025. This compares to the company's previous guidance of $450.0 million to $465.0 million.

BillionToOne also expects to operate the business such that it will continue to generate profitability similar to current levels, even with significant continued investments.

Webcast and Conference Call Information

BillionToOne will host a conference call today, November 4, 2026, at 1:30pm Pacific Time / 4:30pm Eastern Time. Investors interested in listening to the conference call are required to register online. A live and archived webcast of the event for interested listeners can be accessed at

https://investors.billiontoone.com/.

About BillionToOne

Headquartered in Menlo Park, California, BillionToOne is a molecular diagnostics company with a mission to create powerful and accurate tests that are accessible to all. The company's patented Quantitative Counting Templates™ (QCT™) molecular counting platform is the only multiplex technology that can accurately count DNA molecules at the single-molecule level.

Forward-Looking Statements

This press release contains certain forward-looking statements within the meaning of federal securities laws. These forward-looking statements generally are identified by the words “believe,” “project,” “expect,” “anticipate,” “estimate,” “intend,” “strategy,” “future,” “opportunity,” “plan,” “may,” “should,” “will,” “would,” “will be,” “will continue,” “will likely result,” and similar expressions. Forward-looking statements are predictions, projections and other statements about future events that are based on current expectations and assumptions and, as a result, are subject to risks and uncertainties. Forward-looking statements in this press release include, but are not limited to, statements regarding revenue, income and other financial information for the full year of 2026. These statements are based on management’s current expectations, forecasts and assumptions, and actual outcomes and results could differ materially from these statements due to a number of factors, some of which are beyond BillionToOne’s control. These and additional risks and uncertainties that could affect BillionToOne’s financial and operating results and cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. These risks and uncertainties include those discussed under the captions “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in BillionToOne’s most recently filed quarterly report on Form 10-Q, the annual report on Form 10-K and other filings BillionToOne makes with the Securities and Exchange Commission from time to time. The forward-looking statements in this press release are based on information available to BillionToOne as of the date hereof, and BillionToOne disclaims any obligation to update any forward-looking statements provided to reflect any change in its expectations or any change in events, conditions, or circumstances on which any such statement is based, except as required by law. These forward-looking statements should not be relied upon as representing BillionToOne’s views as of any date subsequent to the date of this press release.

Non-GAAP financial measures

We use certain non-GAAP financial measures to supplement our unaudited financial results, which are presented in accordance with GAAP. These non-GAAP financial measures include EBITDA, adjusted EBITDA and free cash flow. By excluding the impact of certain items that we believe do not directly reflect our underlying operations, we are of the opinion that EBITDA, adjusted EBITDA and free cash flow provide meaningful supplemental information regarding our performance. Accordingly, we believe these non-GAAP financial measures are useful to investors and others because they allow for additional information with respect to financial measures used by management in its financial and operational decision-making and forecasting. These metrics also provide investors and other users of our financial information with additional tools to compare business performance across companies and periods, while eliminating the effects of items that may vary for different companies for reasons unrelated to core operating performance. However, there are a number of limitations related to the use of non-GAAP financial measures, and these non-GAAP measures should be considered in addition to, not as a substitute for or in isolation from, our financial results prepared in accordance with GAAP. Other companies, including companies in our industry, may calculate these non-GAAP financial measures differently or not at all, which reduces their usefulness as comparative measures. A reconciliation between GAAP and non-GAAP financial information is provided immediately following the financial tables. A reconciliation of the forecasted range for adjusted EBITDA for the full year 2026 is not included in this release due to the number of variables in the projected range and because we are currently unable to quantify accurately certain amounts that would be required to be included in the U.S. GAAP measure or the individual adjustments for such reconciliation.

EBITDA

We define EBITDA as net income (loss) adjusted for income taxes, interest income, interest expense, and depreciation and amortization expense.

Adjusted EBITDA

We define Adjusted EBITDA as net income (loss) adjusted for income taxes, interest income, interest expense, depreciation and amortization expense, and certain other items which include significant non-cash items and events that are highly variable, significant in size, and that we do not believe are indicative of ongoing or future business operations, which include: stock-based compensation expense; change in fair value of term loan; and change in fair value of warrant liabilities.

Free Cash Flow

We define Free Cash Flow as net cash provided by operating activities adjusted for purchases of property and equipment.

BillionToOne, Inc.
Statements of Operations and Comprehensive Income (Loss)
(in thousands, except per share amounts, unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Revenue	$ 122,981	$ 83,523	$ 340,817	$ 209,059
Cost of revenue	35,836	25,107	97,469	69,205
Gross profit	87,145	58,416	243,348	139,854
Operating expenses:				
Research and development	20,216	12,953	52,223	35,134
Selling, general and administrative	55,906	35,830	156,765	99,029
Total operating expenses	76,122	48,783	208,988	134,163
Income from operations	11,023	9,633	34,360	5,691
Other income (expense):				
Interest income	4,912	1,535	14,251	4,492
Interest expense	(6)	(20)	(24)	(92)
Change in fair value of term loan	1,482	(3,936)	(5,747)	(7,038)
Other income (expense), net	(19)	(1,630)	579	(1,591)
Total other income (expense)	6,369	(4,051)	9,059	(4,229)
Income before provision for income taxes	17,392	5,582	43,419	1,462
Provision for income taxes	1	(129)	4	(15)
Net income	$ 17,391	$ 5,711	$ 43,415	$ 1,477
Less: Net income attributable to participating securities	-	(4,204)	-	(1,089)
Net income attributable to common stockholders	$ 17,391	$ 1,507	$ 43,415	$ 388
Other comprehensive income, net of taxes:				
Change in fair value of term loan attributable to instrument-specific credit risk	$ (1,069)	$ -	$ (1,069)	$ -
Other comprehensive loss, net of taxes	(1,069)	-	(1,069)	-
Comprehensive income, net of taxes	$ 16,322	$ 5,711	$ 42,346	$ 1,477
Net income per share, basic and diluted:				
Net income per share, basic	$ 0.37	$ 0.14	$ 0.93	$ 0.04
Net income per share, diluted	$ 0.32	$ 0.10	$ 0.81	$ 0.03
Weighted-average shares used in calculating net income per share, basic and diluted:				
Weighted-average shares used in calculating net income per share, basic	47,271,383	10,429,583	46,540,721	10,376,253
Weighted-average shares used in calculating net income per share, diluted	53,732,158	15,571,949	53,743,737	15,117,365

BillionToOne, Inc.
Balance Sheets
(in thousands, except share amounts, unaudited)

	September 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 561,512	$ 495,975
Accounts receivable	88,283	41,617
Inventories	21,891	17,545
Prepaid expenses and other current assets	10,407	5,421
Total current assets	682,093	560,558
Property and equipment, net	26,784	20,361
Operating lease right-of-use assets, net	46,300	46,742
Other non-current assets	5,313	4,993
Total assets	$ 760,490	$ 632,654
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 10,232	$ 7,184
Accrued expenses and other current liabilities	15,018	7,247
Accrued commissions	3,465	3,912
Accrued compensation and employee benefits	22,869	12,551
Common stock warrant liability	—	9,282
Deferred revenue, current	1,884	2,188
Operating lease liabilities, current	6,784	5,079
Financing lease liabilities, current	385	519
Total current liabilities	60,637	47,962
Operating lease liabilities, non-current	44,222	45,723
Financing lease liabilities, non-current	75	348
Deferred revenue, non-current	28	1,290
Long-term debt	88,982	57,226
Total liabilities	193,944	152,549
Stockholders' equity:		
Class A common stock, $0.00001 par value, 800,000,000 shares authorized as of September 30, 2026 and December 31, 2025; 43,128,349 and 41,252,105 shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively	—	—
Class B common stock, $0.00001 par value; 10,000,000 shares authorized as of September 30, 2026 and December 31, 2025; 4,502,650 and 4,552,650 shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively	—	—
Additional paid-in capital	800,739	756,644
Accumulated other comprehensive loss	(2,861)	(1,792)
Accumulated deficit	(231,332)	(274,747)
Total stockholders' equity	566,546	480,105
Total liabilities and stockholders' equity	$ 760,490	$ 632,654

BillionToOne, Inc.
Statements of Cash Flows
(in thousands, unaudited)

	Nine Months Ended September 30,	
	2026	2025
Cash flows from operating activities:		
Net income	$ 43,415	$ 1,477
Adjustments to reconcile net income to net cash provided by operating activities:		
Stock-based compensation	24,430	9,581
Depreciation and amortization	5,540	5,232
Amortization of operating right-of-use assets	4,432	3,715
Loss on disposal of fixed assets	82	7
Change in fair value of common stock warrant liability	(62)	1,409
Change in fair value of redeemable convertible preferred stock warrant liability	-	176
Change in fair value of term loan	687	3,505
Changes in operating assets and liabilities:		
Accounts receivable	(46,666)	(9,937)
Inventories	(4,346)	(8,656)
Prepaid expenses and other current assets	(4,903)	(1,727)
Other non-current assets	(320)	(62)
Accounts payable	4,025	3,047
Accrued expenses and other current liabilities	7,871	3,972
Accrued commissions	(447)	166
Accrued compensation and employee benefits	8,727	5,268
Deferred revenue	(1,566)	(123)
Operating lease liabilities	(3,786)	(3,247)
Net cash provided by operating activities	37,113	13,803
Cash flows from investing activities:		
Purchases of property and equipment	(12,466)	(7,344)
Net cash used in investing activities	(12,466)	(7,344)

BillionToOne, Inc.
Statements of Cash Flows
(in thousands, unaudited)

	Nine Months Ended September 30,	
	2026	2025
Cash flows from financing activities:		
Proceeds from issuance of debt	30,000	-
Principal payments on finance lease liabilities	(407)	(1,449)
Payment of deferred offering costs	(504)	(2,516)
Proceeds from exercise of stock options	12,236	1,181
Taxes paid related to net share settlement of equity awards	(435)	-
Net cash provided by (used in) financing activities	40,890	(2,784)
Net increase in cash and cash equivalents	65,537	3,675
Cash and cash equivalents at beginning of period	495,975	191,477
Cash and cash equivalents at end of period	$ 561,512	$ 195,152
Supplemental cash flow disclosure:		
Cash payments for interest	$ 5,084	$ 3,626
Cash paid for income taxes	$ 393	$ 460
Supplemental cash flow information and non-cash investing and financing activities:		
Purchases of property and equipment in accounts payable and accrued expenses and other current liabilities	$ 1,970	$ 500
Deferred offering costs in accounts payable and accrued expenses and other current liabilities	$ -	$ 1,144
Right-of-use assets obtained in exchange for new operating lease liabilities	$ 4,034	$ -
Cash paid for amounts included in the measurement of operating lease liabilities	$ 7,135	$ 6,594
Net exercise of Class A common stock warrants	$ 9,220	$ -
Operating cash flows from financing leases (interest paid)	$ 24	$ 89
Exercise of stock options for which cash had not been received	$ 86	$ -

BillionToOne, Inc.

Reconciliation of Net Income (Loss) to EBITDA
(in thousands, unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Net income	$ 17,391	$ 5,711	$ 43,415	$ 1,477
Provision for income taxes	1	(129)	4	(15)
Interest (income)	(4,912)	(1,535)	(14,251)	(4,492)
Interest expense	6	20	24	92
Depreciation and amortization	1,973	1,692	5,540	5,232
EBITDA	$ 14,459	$ 5,759	$ 34,732	$ 2,294

Reconciliation of Net Income (Loss) to Adjusted EBITDA
(in thousands, unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Net income	$ 17,391	$ 5,711	$ 43,415	$ 1,477
Provision for income taxes	1	(129)	4	(15)
Interest (income)	(4,912)	(1,535)	(14,251)	(4,492)
Interest expense	6	20	24	92
Depreciation and amortization	1,973	1,692	5,540	5,232
Stock-based compensation expense	9,703	4,475	24,430	9,581
Change in fair value of term loan	(1,482)	3,936	5,747	7,038
Change in fair value of warrant liabilities	-	1,627	(62)	1,585
Adjusted EBITDA	$ 22,680	$ 15,797	$ 64,847	$ 20,498

Reconciliation of Free Cash Flow to Net Cash Provided by Operating Activities
(in thousands, unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Net cash provided by operating activities	$ 12,547	$ 9,996	$ 37,113	$ 13,803
Purchases of property and equipment	(3,946)	(2,123)	(12,466)	(7,344)
Free cash flow	$ 8,601	$ 7,873	$ 24,647	$ 6,459

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