Natera, Inc.

Investor presentation

Q3 2021 earnings call

Safe harbor statement

This presentation contains forward-looking statements under the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical facts contained in this presentation, including statements regarding our market opportunity, our proposed products and launch schedules, our reimbursement coverage and our product costs, our commercial partners and potential acquisitions, our user experience, our clinical trials and studies, our financial performance, our strategies, our anticipated revenue and financial outlook, our goals and general business and market conditions, are forward-looking statements.

These forward-looking statements are subject to known and unknown risks and uncertainties that may cause actual results to differ materially, including: we face numerous uncertainties and challenges in achieving our financial projections and goals; we may be unable to maintain our business and operations as planned due to disruptions and economic uncertainty caused by the COVID-19 pandemic; we may be unable to further increase the use and adoption of Panorama and Horizon through our direct sales efforts or through our laboratory partners; we may be unable to develop and successfully commercialize new products, including Signatera and Prospera; we have incurred losses since our inception and we anticipate that we will continue to incur losses for the foreseeable future; our quarterly results may fluctuate from period to period; our estimates of market opportunity and forecasts of market growth may prove to be inaccurate; we may be unable to compete successfully with existing or future products or services offered by our competitors; we may engage in acquisitions, dispositions or other strategic transactions that may not achieve our anticipated benefits and could otherwise disrupt our business, cause dilution to our stockholders or reduce our financial resources; we may not be successful in commercializing our cloud-based distribution model; our products may not perform as expected; the results of our clinical studies, including our SNP-based Microdeletion and Aneuploidy RegisTry, or SMART, Study, may not be compelling to professional societies or payors as supporting the use of our tests, particularly in the average-risk pregnancy population or for microdeletions screening, or may not be able to be replicated in later studies required for regulatory approvals or clearances; if either of our primary CLIA-certified laboratory facilities becomes inoperable, we will be unable to perform our tests and our business will be harmed; we rely on a limited number of suppliers or, in some cases, single suppliers, for some of our laboratory instruments and materials and may not be able to find replacements or immediately transition to alternative suppliers; if we are unable to successfully scale our operations, our business could suffer; the marketing, sale, and use of Panorama and our other products could result in substantial damages arising from product liability or professional liability claims that exceed our resources; we may be unable to expand, obtain or maintain third-party payer coverage and reimbursement for Panorama, Horizon and our other tests, and we may be required to refund reimbursements already received; third-party payers may withdraw coverage or provide lower levels of reimbursement due to changing policies, billing complexities or other factors, such as the increased focus by third-party payers on requiring that prior authorization be obtained prior to conducting a test; if the FDA were to begin actively regulating our tests, we could incur substantial costs and delays associated with trying to obtain premarket clearance or approval and incur costs associated with complying with post-market controls; litigation or other proceedings, resulting from either third party claims of intellectual property infringement or third party infringement of our technology, is costly, time-consuming and could limit our ability to commercialize our products or services; any inability to effectively protect our proprietary technology could harm our competitive position or our brand; and we cannot guarantee that we will be able to service and comply with our outstanding debt obligations or achieve our expectations regarding the conversion of our outstanding convertible notes. We discuss these and other risks and uncertainties in greater detail in the sections entitled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our periodic reports on Forms 10-K and 10-Q and in other filings we make with the SEC from time to time. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statement. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this presentation may not occur and our actual results could differ materially and adversely from those anticipated or implied. As a result, you should not place undue reliance on our forward-looking statements. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this presentation to conform these statements to actual results or to changes in our expectations. We file reports, proxy statements, and other information with the SEC. Such reports, proxy statements, and other information concerning us is available at http://www.sec.gov. Requests for copies of such documents should be directed to our Investor Relations department at Natera, Inc., 13011 McCallen Pass, Building A Suite 100, Austin, TX 78753. Our telephone number is (650) 249-9090.

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Recent highlights

- Continued outperformance in volumes and revenues:
  - 407,000 tests processed in Q3, 55% growth vs Q3 2020
  - Total revenues of $158M, 61% growth vs Q3 2020
  - Product revenues of $151M, up 62% vs Q3 2020
- Raising revenue guide again: was $600M – $620M, now $615M – $625M, increase of $100M from start of year
- Launched Prospera with Quantification in kidney transplant supported by JASN publication and Trifecta study
- Announced initial positive results from the Trifecta Study, the largest prospective multi-site fully biopsy matched study
- Major expansion in organ health with commercial launch of Prospera Heart and Prospera Lung:
- Announced new publication validating Signatera velocity metric to improve cancer management
- Signatera selected for NRG Oncology ‘s landmark CIRCULATE-US study
- BGI announced use of Signatera in prospective GI cancer trial in China
- Secured access to a biobank of 40K prospectively collected colorectal cancer screening samples from Aarhus University for development and validation of a test in early cancer detection

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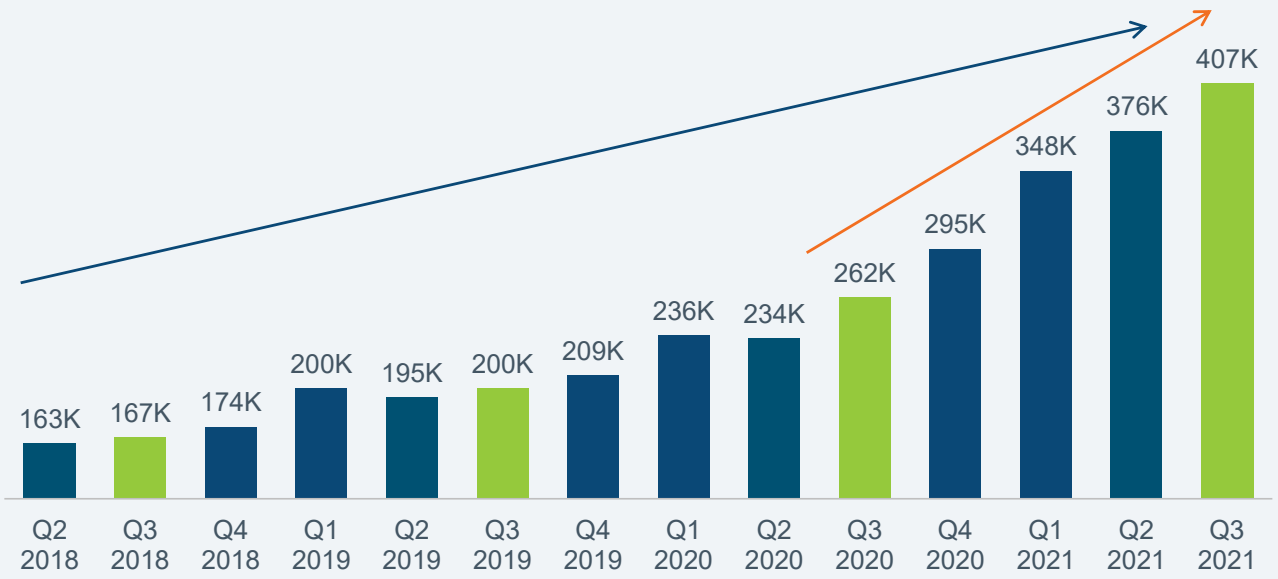
Q3 volume momentum continues: 407,000 units in Q3

- ~ 55% volume growth over Q3 2020
- Continued momentum across all products

Total processed units



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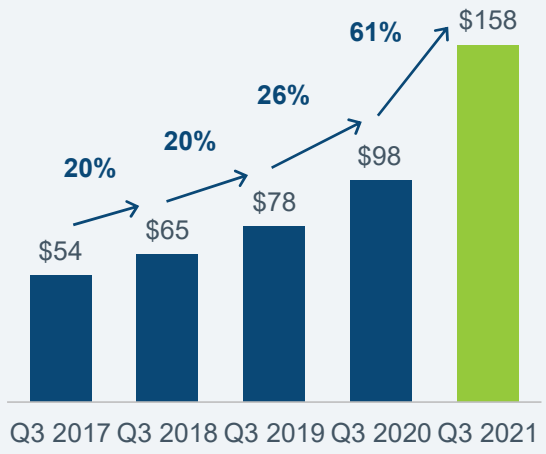
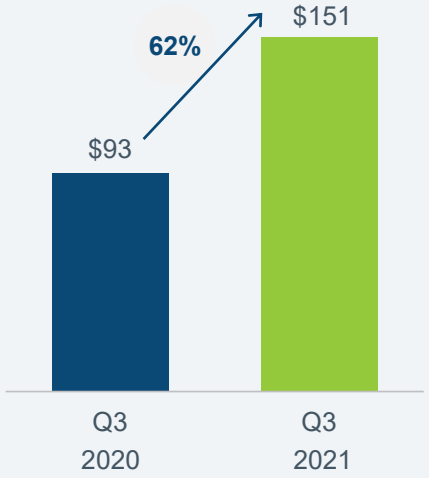
Accelerating revenues

- Volume-out performance combined with improving ASPs
- New products gaining momentum

Total revenues ($ in millions)



Product revenues[1] ($ in millions)



1. Excludes licensing and other revenues

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Organ Health updates

- Prospera Kidney, Heart and Lung commercially available
- Large multi-site prospective data available
- Innovation driving exceptional AUC's



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Prospera Kidney gaining significant market adoption

45 of the top 100 transplant centers routinely using Prospera

~2,500 patients enrolled in ProActive Registry trial

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Only Prospera Kidney offers quantification

$$\frac{\text{Absolute quantity of dd-cfDNA (copies per mL)}}{\text{Total quantity of cfDNA (copies per mL)}} = \left(\text{\% dd-cfDNA} \right)$$

Factors that may influence total cfDNA[1-10]

- High body mass index
- Infection
- Age
- Surgery
- Shipment & storage
- Chemotherapy
- Normal variation
- Myocardial infarction
- Hemodialysis
- Rejection

1. Vora N., et al. (2012). Prenat Diagn., 32(9):912–914. doi:10.1002/pd.3919
2. Ahmed A., et al. (2016). Clin Lab., 62(12):2395-2404.
3. Anker, P., et al. (2000). Medicina (B Aires), 60, 99–702.
4. Qi, Y., et al. (2016). Anesthesiology Research and Practice Volume 2016:2794364.
5. Page, K., et al. (2013). PLoS One 8(10):e77963. doi: 10.1371/journal.pone.0077963
6. Swystun, L. et al. (2011). Journal of Thrombosis and Haemostasis, 9:2313–2321.
7. Stroun, M., et al. (2001). Clin Chim Acta, 313(1-2): 139–142.
8. Chang, R., et al. Chimica Acta, 327(1-2):95-101.
9. Tovbin, N., et al. (2012). Nephrology Dialysis Transplantation, 27(10), 3929-3935

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Prospera with Quantification improves sensitivity

JASN Journal of the American Society of Nephrology

Original method with dd-cfDNA fraction			Performance of the enhanced algorithm[1]		
Overall sensitivity	7 / 9	77.8%	Overall sensitivity	9 / 9	>99%
Specificity	29 / 32	90.6%	Specificity	28 / 32	87.5%

1. Bunnapradist, S. Using both fraction and quantity of donor-derived cell-free DNA to detect kidney allograft rejection, J Amer Soc Nephrology 2021

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Results from Trifecta Study further validates Prospera with Quantification

Largest prospective fully biopsy-matched, multi-site cohort of dd-cfDNA for kidney transplant recipients[1]

Details of study

- More than 300 biopsy-matched samples
- Over 100 biopsy-confirmed rejections
- From more than 20 US & international sites



Philip Halloran, MD, PhD
Distinguished University Professor
Department of Medicine,
Division of Nephrology and Transplant Immunology, University of Alberta

Key results:

	Area under the curve
Rejection from non-rejection using BANFF 2019 as truth	**0.81**
Rejection from non-rejection using molecular pathology as truth	**0.89**
Rejection from 'quiescence' using BANFF 2019 as truth[2]	**0.91**

1. Halloran, et al. Manuscript in preparation, 2021
2. Quiescence: No signs of rejection on pathology or DSA

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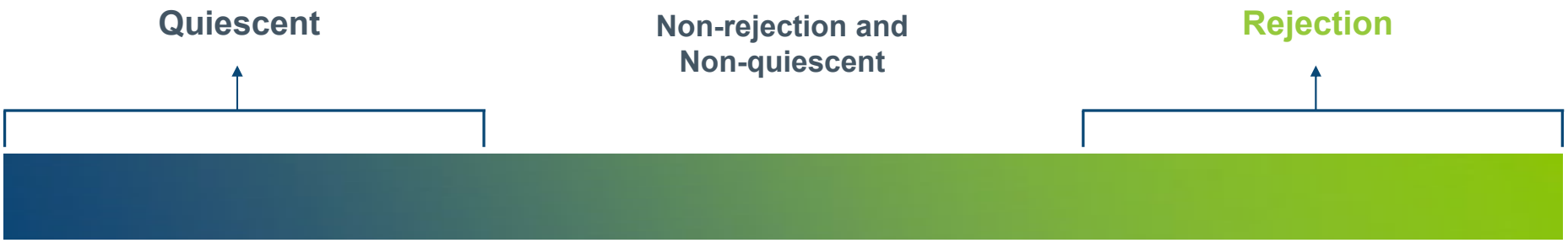
Limitations of rejection vs quiescence

Most publications compare rejection to non-rejection, recent multi-modality studies compare rejection to 'quiescent' patients (only the most clinically stable of non-rejection patients)



"The limitations of the current study include the number of rejection samples and limited scope of the patient population." - Akalin, et al.

"The authors specifically excluded biopsies that contained other common pathologies found in kidney allografts—including infection, chronic tubular injury/fibrosis, calcineurin inhibitor toxicity, recurrent primary disease, and others—that could confound the diagnostic utility of the assays. How the two assays will behave in a more heterogeneous and unselected cohort remains unclear." - Khilnani, et al.

Akalin, et al. Clinical Validation of an Immune Quiescence Gene Expression Signature in Kidney Transplantation. Kidney360 September 2021, 10.34067/KID.0005062021; https://doi.org/10.34067/KID.0005062021
Khilnani, et al. Two can be better than one: Improving Non-invasive Diagnostics in Kidney Transplantation. CJASN 16: 1462 - 1463, 2021; https://doi.org/10.2215/CJN.10630821

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Launch of the Prospera Heart transplant assessment test

Validation of a novel donor-derived cell-free DNA assay for the detection of acute rejection in heart transplantation[1]

- In partnership with University of Utah and University of California, San Diego
- Included >250 samples from a prospective trial run in 2020-2021
- Combined with a >100 sample cohort of previously collected samples
- Total validation study size >350 samples



Area under the curve	**0.844**
Area under the curve with Quantification	**0.88**

- Single, noninvasive test with excellent performance
- Easy-to-use: no spin down or shipment on dry ice
- Less cost to the system

1. Kim et al, Manuscript submitted for publication

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Launch of the Prospera lung test-validation results presented at CHEST 2021

CHEST Annual Meeting

Largest prospective trial of commercial dd-cfDNA test for lung transplant assessment[1]

- Performed in collaboration with Ohio State University
- 195 samples
- 103 patients
- 35 biopsy confirmed acute rejection cases



Results from the VALID study[1]

	Area under the curve
Acute rejection vs stable	**0.91**
Acute/chronic rejection or infection vs stable	**0.76**

1. Natera clinical validation data. Publication pending

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Announcing asymptomatic screening program

AARHUS UNIVERSITY

About the study

- Planned study with access to up to 40,000 prospectively collected colorectal cancer screening samples with matched outcomes data
- More than 50% of affected cases collected in Stage I / Stage II
- Exclusive option to license IP, access to Aarhus' methylation signature data
- Multi factor technology approach: DNA signature derived from thousands of proprietary exomes + methylation signature
- Potential to add additional cancer types in the study

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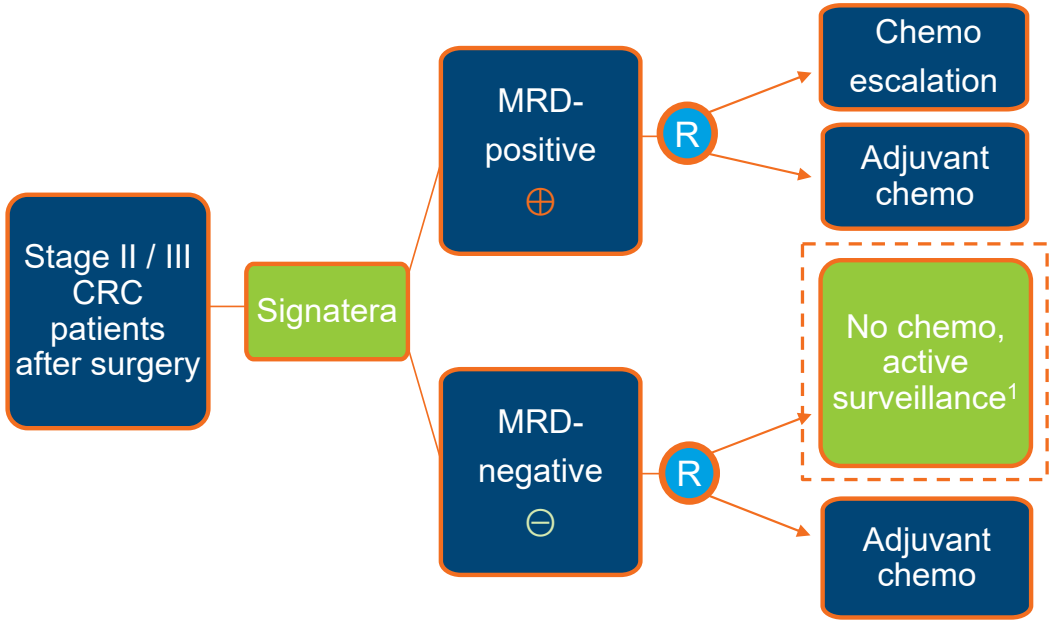
Signatera selected for landmark CIRCULATE-US Study

- US arm of international CIRCULATE trial for colorectal cancer, enrolling ~2,000 patients
- Primary endpoint disease free survival
- Definitive prospective US trial for MRD-guided management of CRC

Post-operative management of stage II / III CRC patients using Signatera



1. Patients in Cohort A (Arm 2) who develop a ctDNA positive assay during serial monitoring may transition to the ctDNA positive cohort (Cohort B) and undergo a second randomization

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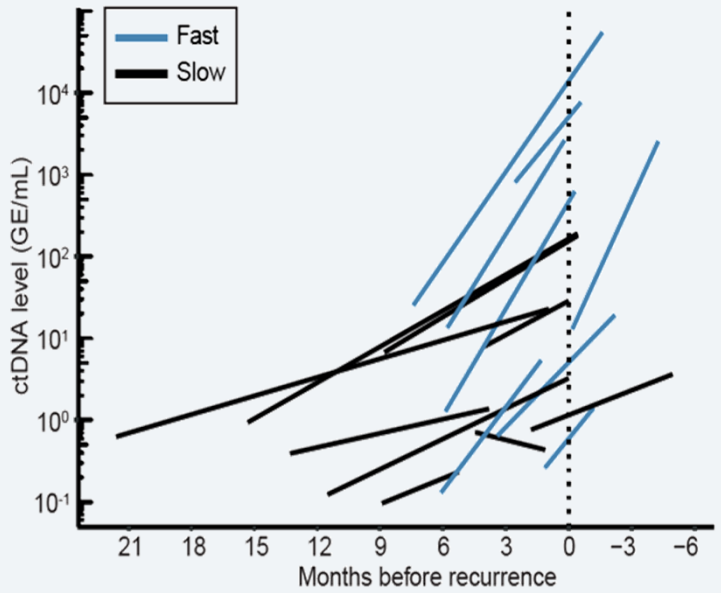
Data validates Signatera velocity metric

Clinical Cancer Research

Prospective phase III trial[1]:

- **168 stage III CRC patients** undergoing curative intent treatment
- **MRD assessment** before and after surgery, and then at regular intervals throughout adjuvant chemotherapy (ACT) and surveillance for up to 3 years

Tumor growth type	ctDNA rate of change	3-year overall survival
Slow	27% increase/mo.	100%
Fast	137% increase/mo.	43%



Only MRD test on the market validated for tumor velocity measurement

1. Henriksen TV, et al., Circulating tumor DNA in stage III colorectal cancer, beyond minimal residual disease detection, towards assessment of adjuvant therapy efficacy and clinical behavior of recurrences. Clin Cancer Res. 2021

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Q3 financial overview

($ in millions, except for per share data)

P&L	Q3'21	Q3'20	Change
Product revenues	$150.7	$93.3	$57.4
Licensing and other revenues	$7.5	$4.9	$2.6
Total revenues	$158.1	$98.1	$60.0
Gross margin% [1]	48.5%	47.2%	134 bps
R&D	$98.5	$26.4	$72.1
SG&A	$128.5	$75.7	$52.8
Net loss per diluted share	($1.63)	($0.72)	($0.91)

Balance sheet	Sep 30, 2021	Jun 30, 2021	Change Q/Q
Cash & investments[2]	$1,023.9	$580.5	$443.4
UBS line of credit	$50.0	$50.0	-
Convertible senior notes[3]	$280.1	$279.8	$0.3

1. Gross margin is calculated as gross profit divided by GAAP total revenues. Gross profit is calculated as GAAP total revenues less GAAP cost of revenues.
2. Cash and investments also include cash equivalents and restricted cash.
3. This balance reflects net carrying value for the Convertible Senior Notes under ASC 470-20 while the gross principal amounts outstanding is $287.5 million as of September 30, 2021.

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Raising 2021 revenue guidance again

Guide $ (millions)	Original	Q1 Guide	Q2 Guide	Current	Key drivers
Revenue	$500 – $525	$550 – $575	$600 – $620	$615 – $625	Continued volume & ASP momentum
Gross margin % revenue	47% – 52%	52% – 55%	52% – 55%	49% – 52%	Strong NIPT margins balanced by growth-related costs in new products
SG&A	$430 – $450	$440 – $460	$500– $520	$500 – $520	Commercial investments ramping as planned
R&D	$160 – $180	$165 – $185	$220 - $230	$240 - $260	Accelerating MRD clinical trials, oncology product launches
Cash burn	$230 - $250	$230 - $250	$300 - $340	$300 - $340	Balance sheet remains strong

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