



Corporate Presentation

November 2021
Nasdaq: BDSI

Forward Looking Statement

CAUTIONARY NOTE ON FORWARD-LOOKING STATEMENTS

This presentation and any statements of employees, representatives, and partners of BioDelivery Sciences International, Inc. (“BDSI”) related thereto contain, or may contain, among other things, certain “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve significant risks and uncertainties. Such statements may include, without limitation, statements with respect to BDSI’s plans, objectives, projections, expectations and intentions and other statements identified by words such as “projects,” “may,” “will,” “could,” “would,” “should,” “believes,” “expects,” “anticipates,” “estimates,” “intends,” “plans,” “potential” or similar expressions. These statements are based upon the current beliefs and expectations of BDSI’s management and are subject to significant risks and uncertainties, including those detailed in BDSI’s filings with the Securities and Exchange Commission. Actual results including, without limitation, the expectations for total company net sales, BELBUCA net sales, operating expenses, EBITDA and operating cash flows in 2021, the planned launch of ELYXYB including net sales of ELYXYB and potential expansion opportunities for ELYXYB, may differ materially from those set forth or implied in the forward-looking statements. These forward-looking statements involve certain risks and uncertainties that are subject to change based on various factors (many of which are beyond BDSI’s control) including the risk that the current COVID-19 pandemic impacts on our supply chain, commercial partners, patients and their physicians and the healthcare facilities in which they work, and our personnel are greater than we anticipate, as well as those set forth in our 2020 annual report on Form 10-K filed with the US Securities and Exchange Commission and subsequent filings. BDSI undertakes no obligation to publicly update any forward-looking statements, whether as a result of new information, future presentations or otherwise, except as required by applicable law.

Non-GAAP Financial Measures

This presentation includes information about certain financial measures that are not prepared in accordance with generally accepted accounting principles in the United States, or GAAP, including non-GAAP net income and EBITDA. These non-GAAP measures are not based on any standardized methodology prescribed by GAAP and are not necessarily comparable to similar measures presented by other companies.

Non-GAAP net income adjusts for one-time and non-cash charges by excluding the following from GAAP net income: stock-based compensation expense, non-cash amortization of intangible assets, and the financial impact of certain one-time items that are non-recurring, including the discontinuation of marketing of BUNAVAIL, and costs associated with the CEO transition in Q2 2020.

EBITDA excludes net interest, including both interest expenses and interest income, provision for (benefit from) income taxes and depreciation and amortization.

The Company’s management and board of directors utilize these non-GAAP financial measures to evaluate the Company’s performance. The Company provides these non-GAAP measures of the Company’s performance to investors because management believes that these non-GAAP financial measures, when viewed with the Company’s results under GAAP and the accompanying reconciliations, are useful in identifying underlying trends in ongoing operations. However, non-GAAP net income and EBITDA are not measures of financial performance under GAAP and, accordingly, should not be considered as alternatives to GAAP measures as indicators of operating performance. Further, non-GAAP net income and EBITDA should not be considered measures of our liquidity.

A reconciliation of certain GAAP to non-GAAP financial measures has been provided in the tables included in the appendix of this presentation.

Growing Commercial-Stage Specialty Pharma Company

Solid Business Fundamentals

- Focused on clinically differentiated products addressing unmet needs
- Strong formulary coverage for BELBUCA and Symproic

Strong Product Momentum

- Significant year over year growth in TRxs
- Continued success utilizing digital tools with in-person engagements increasing

Well-Positioned for Future Strategy

Acquisition of ELYXYB expands BDSI's Growth Platform into Neurology:

- Highly attractive opportunity to diversify our product portfolio
- FDA Approved, Commercially Ready Asset
- Q1 2022 Launch Planned

Strong Performance in Q3 2021 and Positioned Well for Future Growth

Record Market Shares for BELBUCA & Symproic and Record BELBUCA Net Sales



Record Product Market Share

- BELBUCA **4.9%**
- Symproic **13.6%**

Record BELBUCA Net Sales in Q3



- Attractive 27% EBITDA Margin
- \$100.7M Cash Balance
- \$27.3M Operating Cash Flow Year to date 2021
- GAAP EPS \$0.07 vs \$0.05 consensus
- Strong balance sheet to support BDSI's growth



ELYXYB Acquisition Expands BDSI's Presence in Neurology

Product Launch On Track for Q1 2022

Significant Unmet Need in Chronic Pain

Represents Large Potential Market



**High Prevalence
& Quality-of-Life Impact**

1 IN 5 US ADULTS

suffers from chronic pain¹

19.6 MILLION

Adults report high-impact chronic pain*¹



**Long-acting Opioids (LAO)
Remains a Large
Prescription Market****

10.8 MILLION

Prescriptions written for long-acting
opioids in 2020²



\$2.9 BILLION

Total annual LAO sales in 2020²



1. *Chronic pain limiting life or work activities on most days or every day in the past 6 months.

2. **SAO use measured as opioid prescriptions of duration 3 days or fewer. LAO use measured as prescriptions for ER/LA opioid formulations.

¹CDC's analysis of 2016 National Health Interview Survey (NHIS) data.

²Source: Symphony Metys Data, & Symphony Vantage Application (Retail, Mail Order & LTC Data)

BELBUCA



Physicians Attracted by BELBUCA's Efficacy and Safety in Managing Chronic Pain

240k+ patients and **30k+** prescribers to date¹

BELBUCA is indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment for which alternative treatment options are inadequate

- ✓ Proven efficacy
- ✓ Placebo like tolerability in clinical trials*
- ✓ Respiratory ceiling effect
- ✓ Range of 7 dose strengths

BELBUCA's classification as a Schedule III drug allows for strategic advantages over other Schedule II opioids

- ✓ Multiple refills allowed without a new prescription
- ✓ Ability for physicians to prescribe via telehealth

BELBUCA patent exclusivity through January 2027

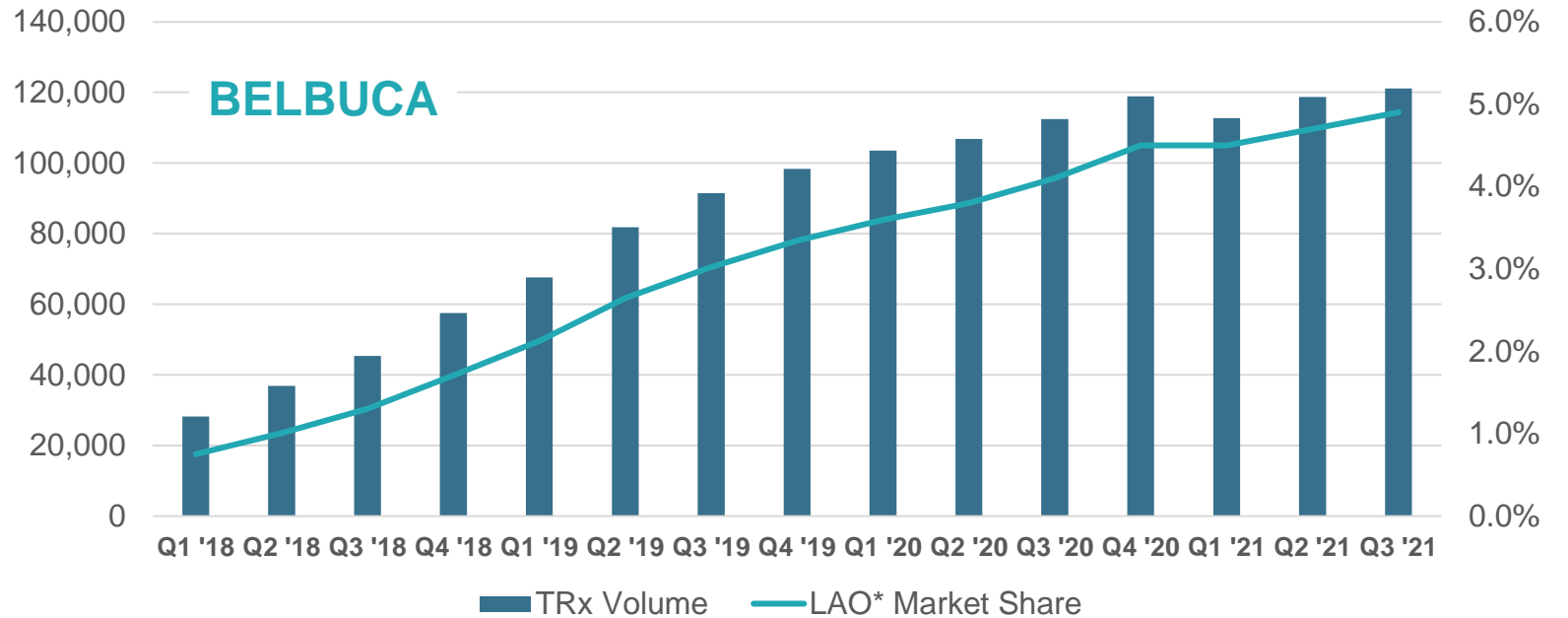
Significant YoY Growth in BELBUCA TRx Volume

BELBUCA Achieved All-Time High TRx Market Share

Growth Metrics

+7.7% Q3 2021 vs Q3 2020

+2.0% Q3 2021 vs Q2 2021



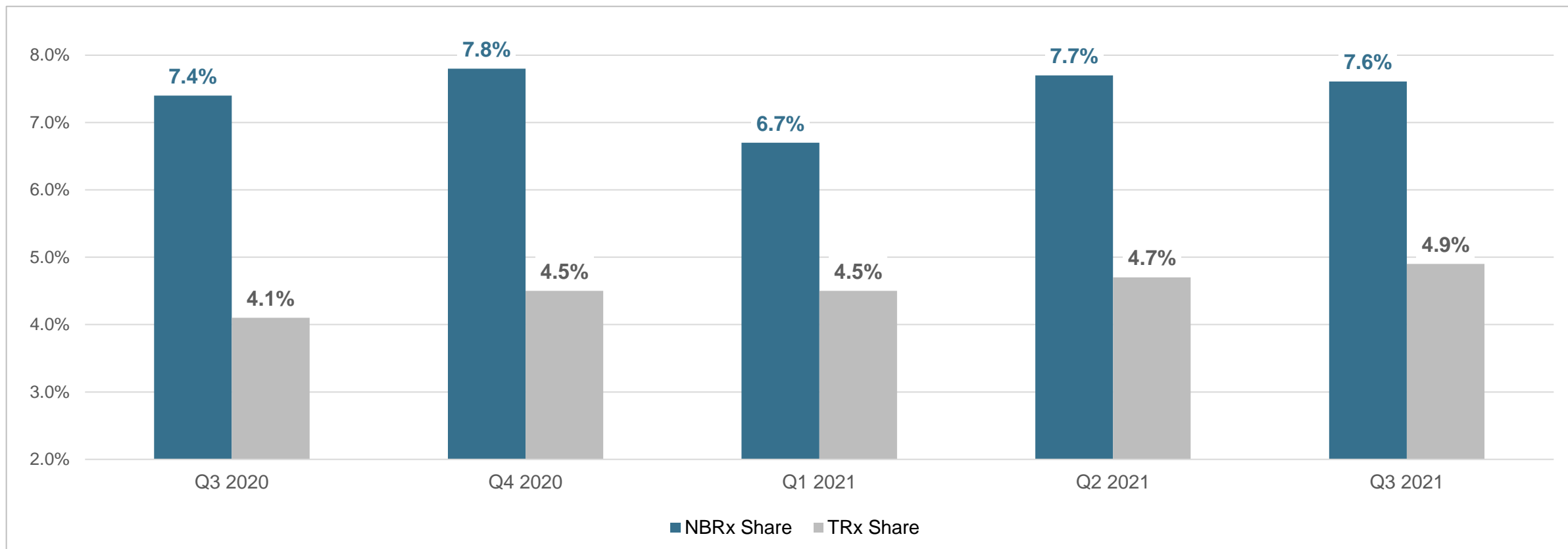
Growing BELBUCA's TRx Market Share through effective execution and marketing support

BELBUCA TRx share increased by 19.5% YoY to 4.9% of the LAO market in Q3 2021

- Successful field and marketing execution generating higher New-to-Brand Rx share
- Total Rx share is increasing due to broader adoption by Healthcare Professionals

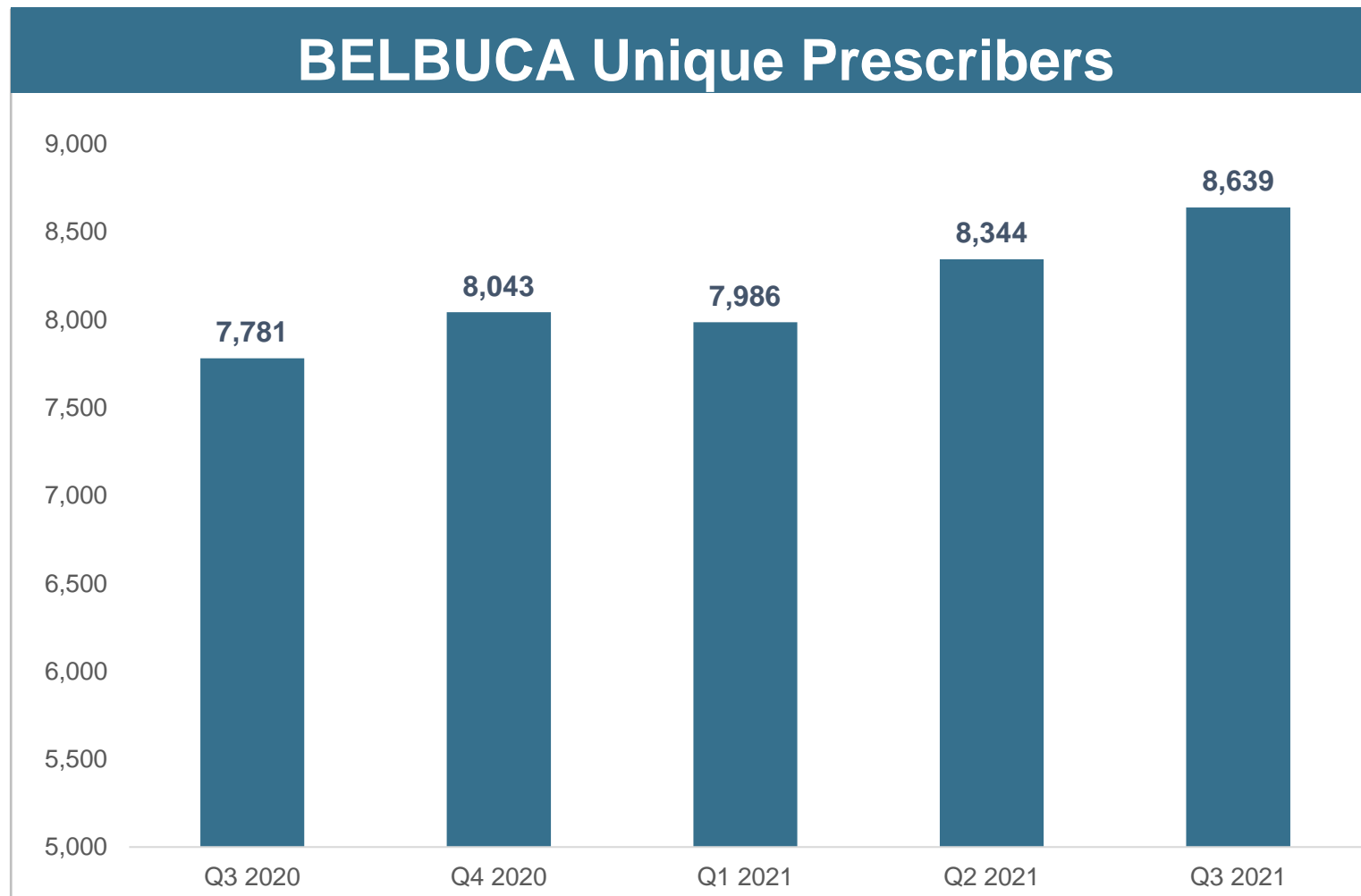
BELBUCA NBRx Share Well Above TRx Share

Indicative of Future Growth Potential

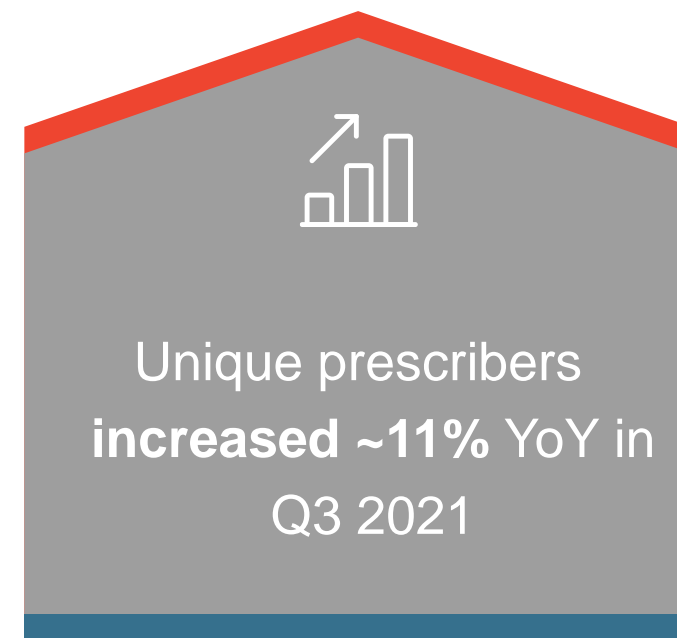


✓ Difference in NBRx & TRx represents opportunities for substantial growth in total prescription share.

BELBUCA Reached A New High for Prescribers in Q3 2021

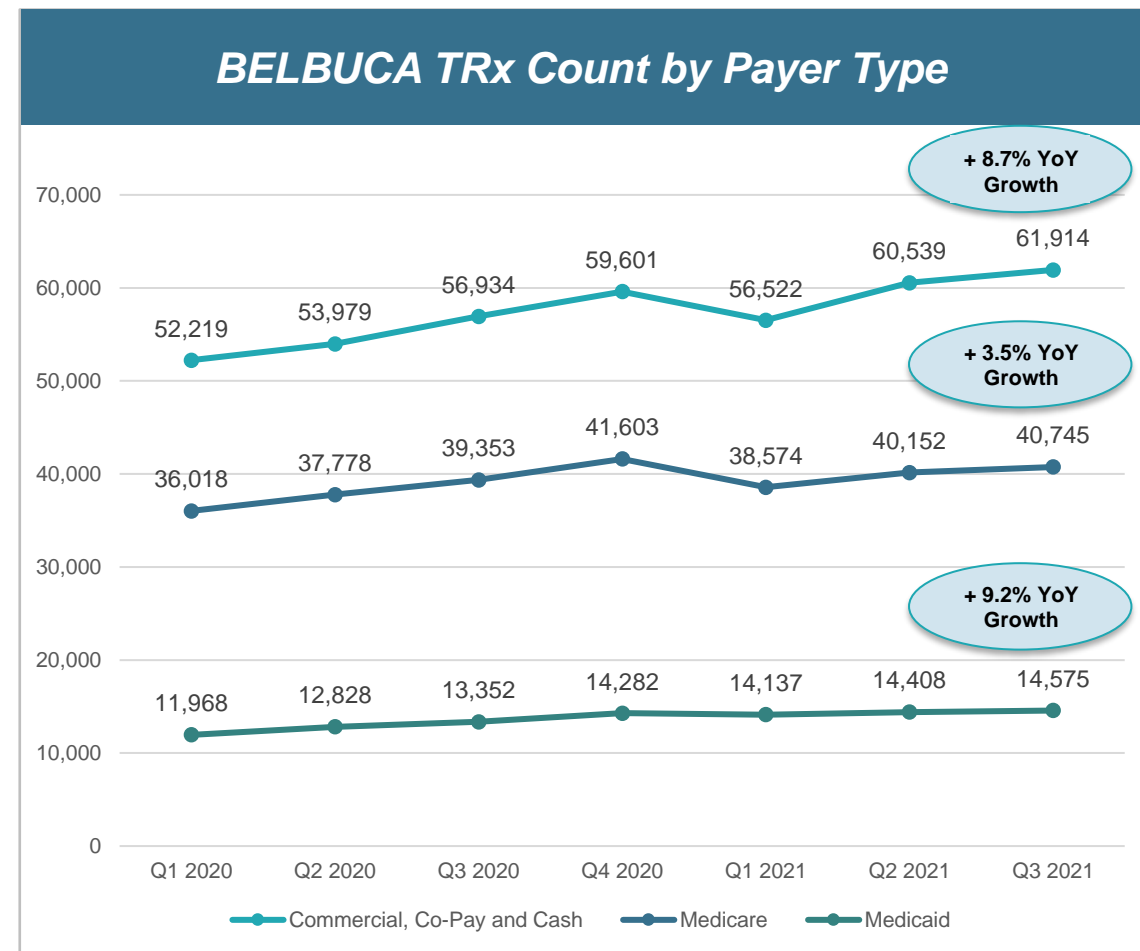
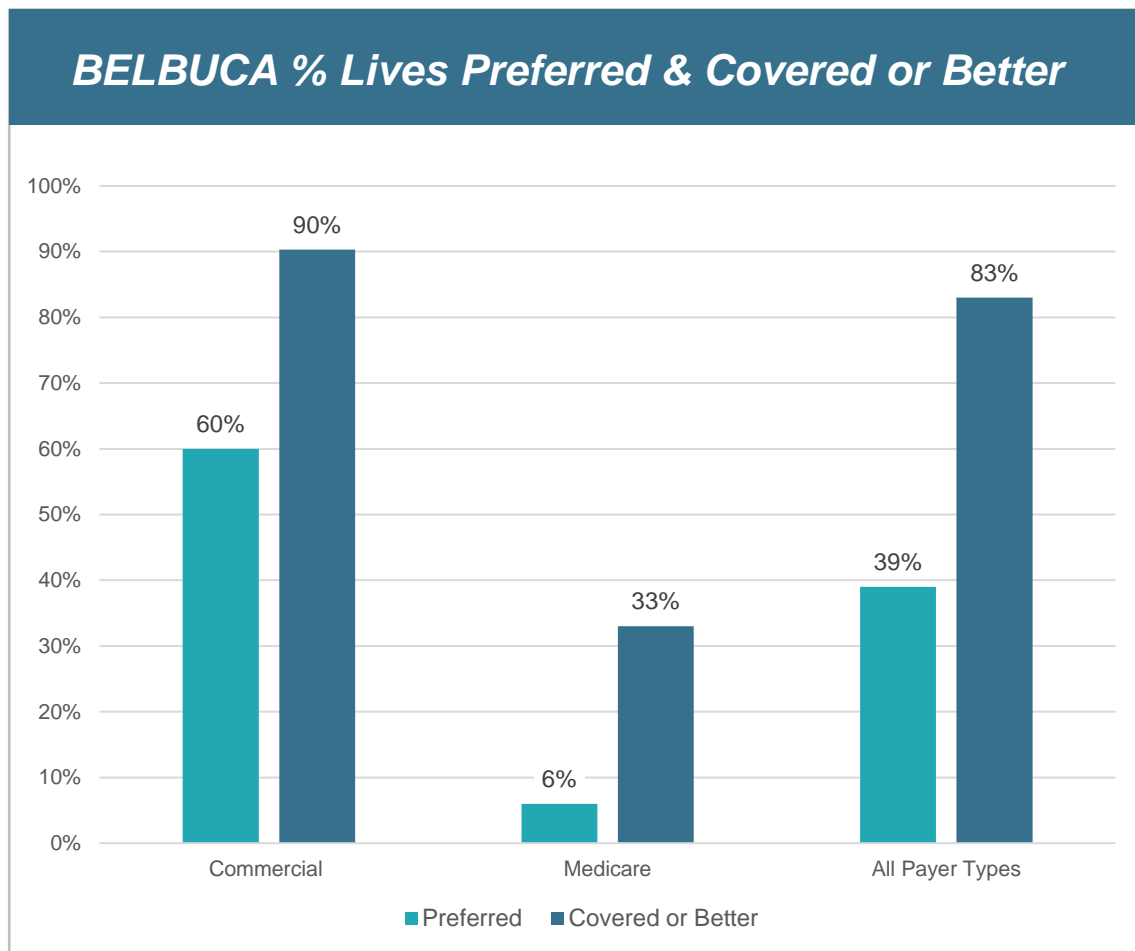


Adding 1,000+
New Prescribers for each
of the last 10 quarters



BELBUCA Enjoys Strong Formulary Coverage

History of Consistent Year Over Year Growth Across All Payer Types



Growing Policy Acceptance for Buprenorphine

HHS Task Force



HHS Task Force
Report on Management
of
Chronic Pain (based on
input from 30+ health /
regulatory agencies)
recommended:

Recommendation 4A:

Make buprenorphine treatment for chronic pain available for specific groups of patients and **include buprenorphine in third-party payer and hospital formularies.**²

Recommendation 4B:

Encourage CMS and private payers to **provide coverage and reimbursement for buprenorphine treatment**, both for OUD and for chronic pain. **Encourage primary use of buprenorphine** rather than use only after failure of standard Mu agonist opioids such as hydrocodone or fentanyl, if clinically indicated.³

Health and Human Services (HHS) Task Force chartered by Congressional legislation and chaired by HHS includes more than 30 representatives from across federal government agencies, including: U.S. Food and Drug Administration • Centers for Disease Control and Prevention (CDC) • National Institutes of Health (NIH) • Office of National Drug Control Policy (ONDCP) Substance Abuse and Mental Health Services Administration (SAMHSA) • U.S. Department of Defense (DOD) • U.S. Department of Veterans Affairs (VA)

1 - Pain Management Best Practices Inter-agency Task Force Report Final Report May 2019

2, 3 - Pain Management Best Practices Inter-agency Task Force Report Final Report May 2019 – Page 29

OIC Affects ~50% of Patients Taking a Class II Opioid¹



Up to 84%

of patients with Opioid Induced Constipation (OIC) report negative impact on their quality of life²

Challenges with Leading Therapies

- 94% of patients who took OTC laxatives* reported an inadequate response³
- Challenges with leading prescription products
 - Must be taken with food
 - Must stop use of laxatives
 - Associated with 20% instance of abdominal pain in starting dose⁴

*Defined as using at least one laxative ≥ 4 times over the previous two weeks

1. Market Research: Segmenting OIC Patient Universe.

2. When People with Opioid-Induced Constipation Speak: A Patient Survey & Patient Preferences for Change in Symptoms Associated with Opioid-Induced Constipation, N = 513 OIC Patients.

3. Opioid-induced constipation in patients with chronic noncancer pain in the USA, Canada, Germany, and the UK; N = 198

4. Movantik Prescribing Information.

Symproic[®] Offers Differentiated Profile in Treating OIC

Symproic Blocks the Opioid Receptors in the Gut, Attacking OIC at its Source While Allowing the Opioid to Effectively Target the Patient's Pain

The PAMORA with More Flexibility¹¹

Once Daily



(Tablet is actual size)

Any time of day



With or without laxatives



With or without food



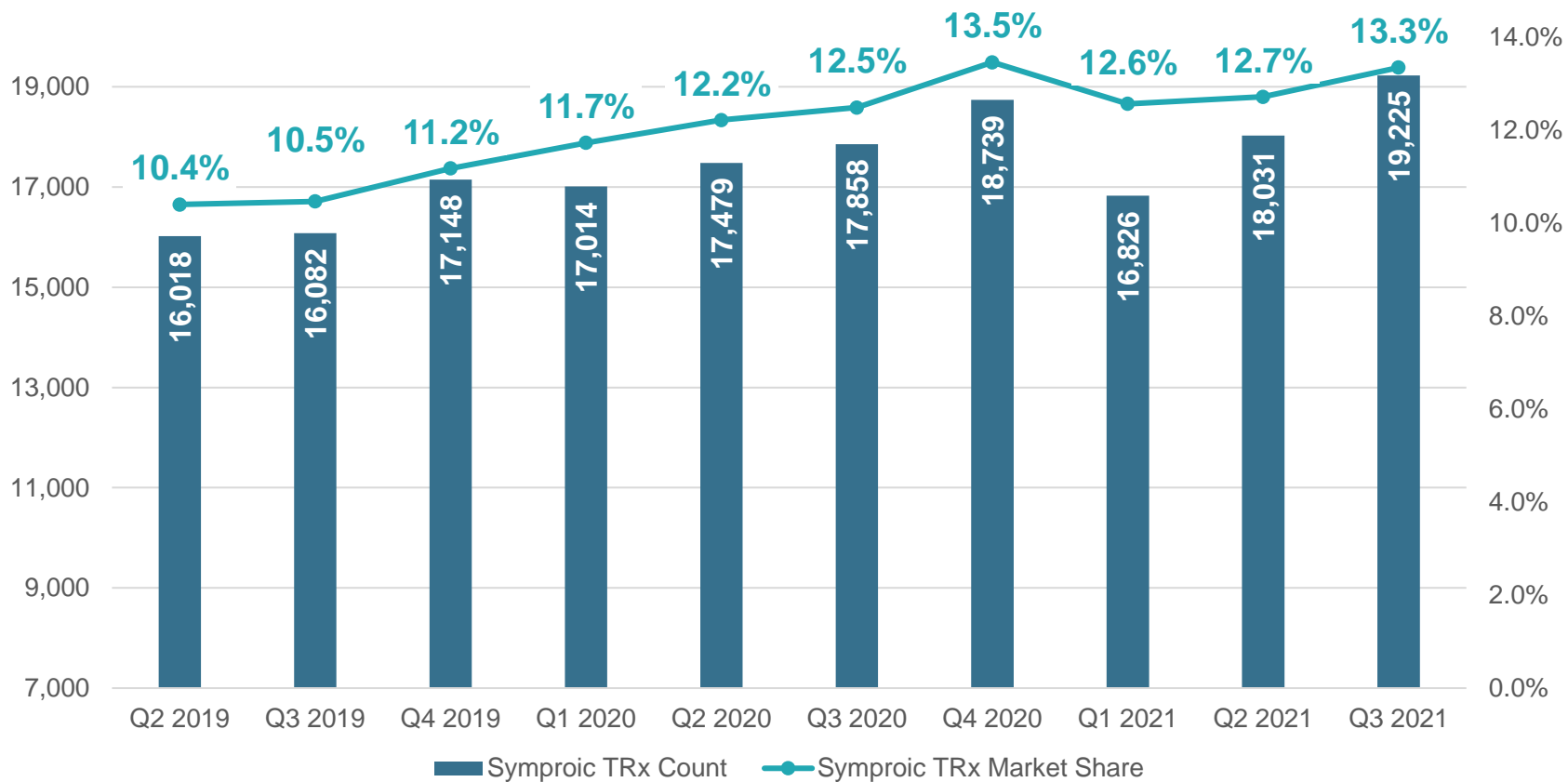
 **Symproic[®]**
(naldemedine) tablets
0.2 mg

- Has strong clinical evidence with robust long-term efficacy and tolerability
- Carries the highest recommendation from the American Gastroenterological Association
- Ideal complementary asset to BELBUCA and is promoted to overlapping HCP targets
- Allows for samples
- Patent Exclusivity through 2031



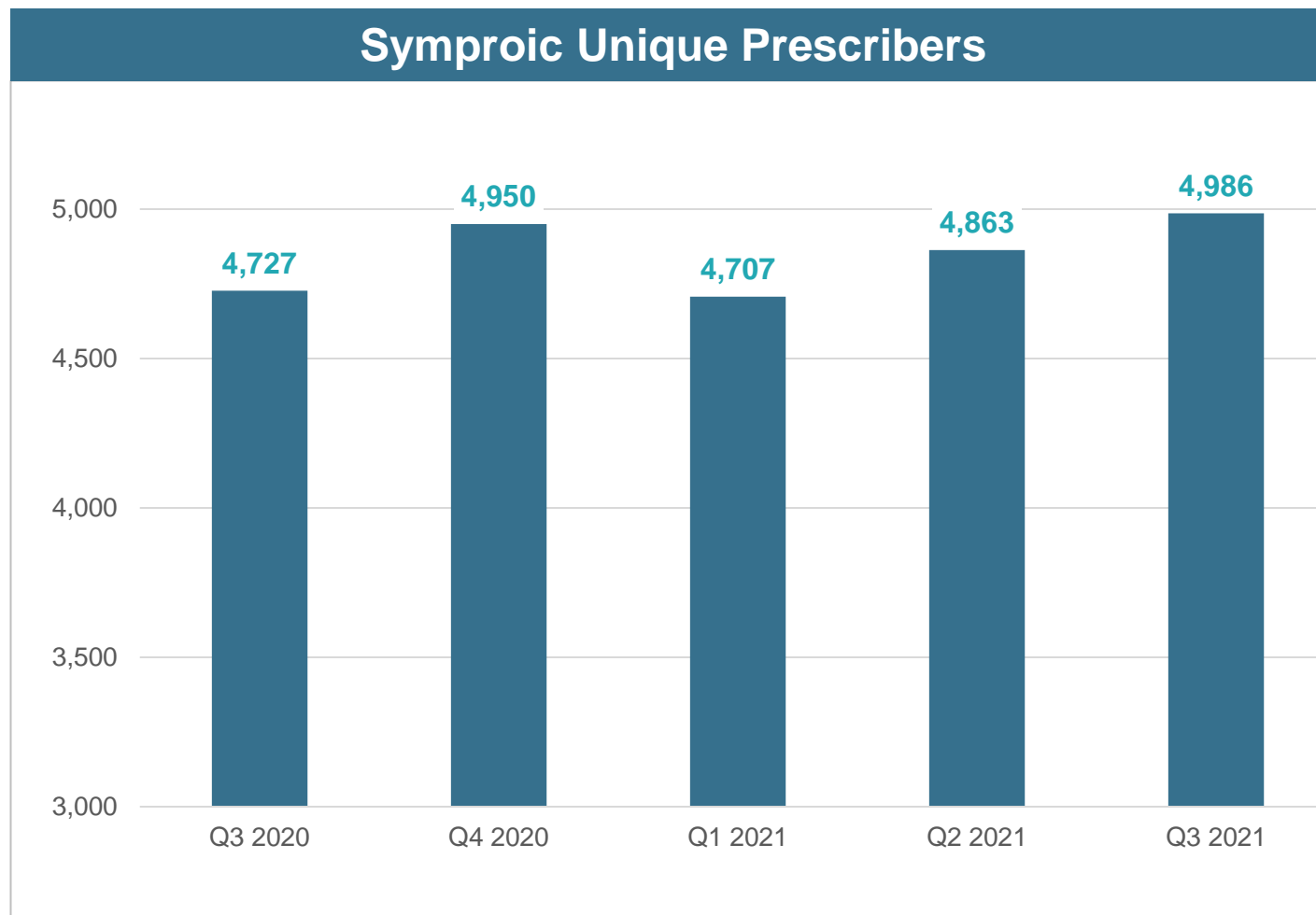
Symproic® TRx Count & Share Since Acquisition

Symproic Quarterly TRx Count & TRx Share of PAMORA* Market

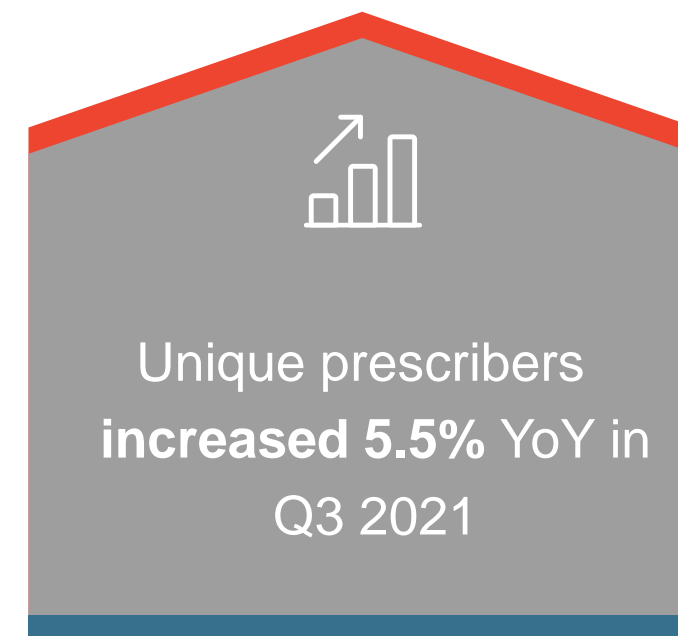


Another strong quarter of
~7% QoQ growth in TRx
 count

Unique Prescribers for Symproic Remain Encouraging



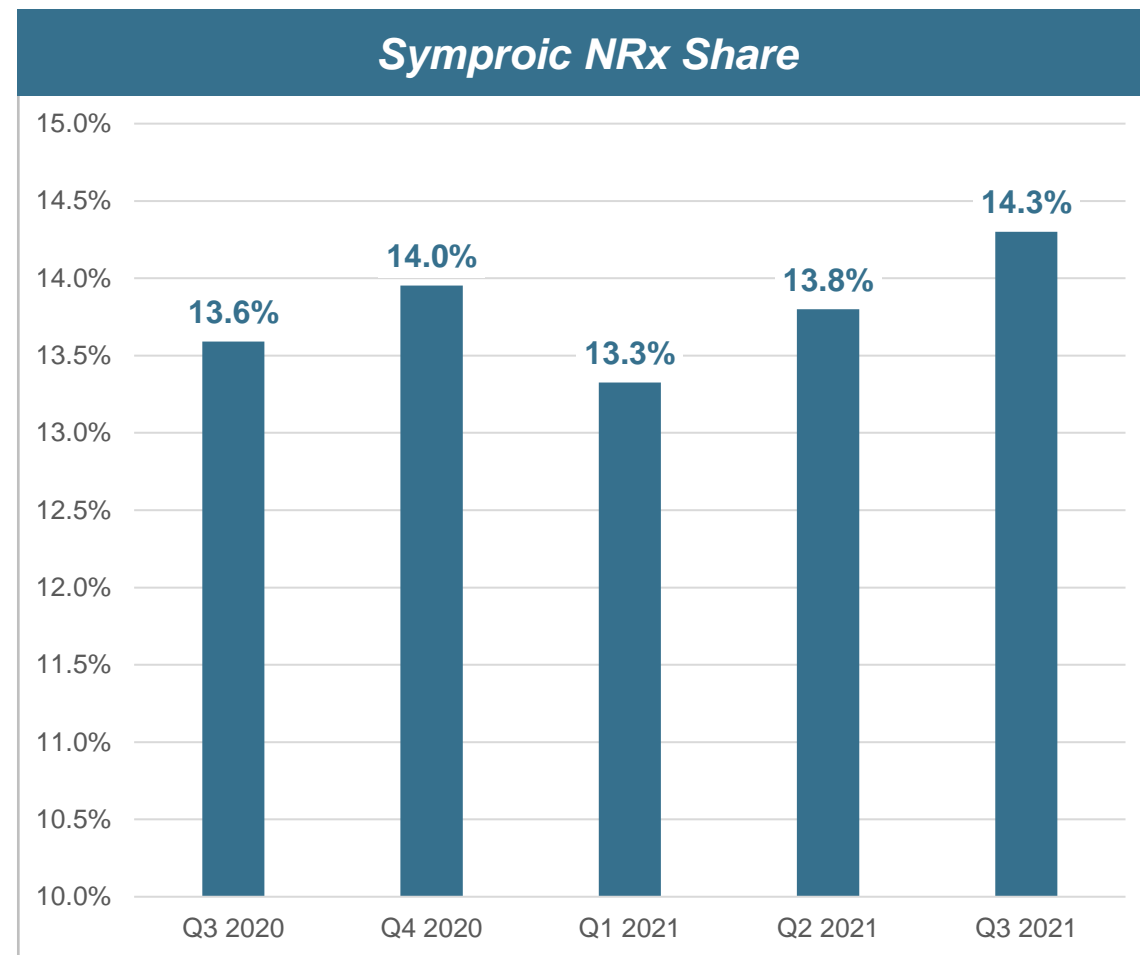
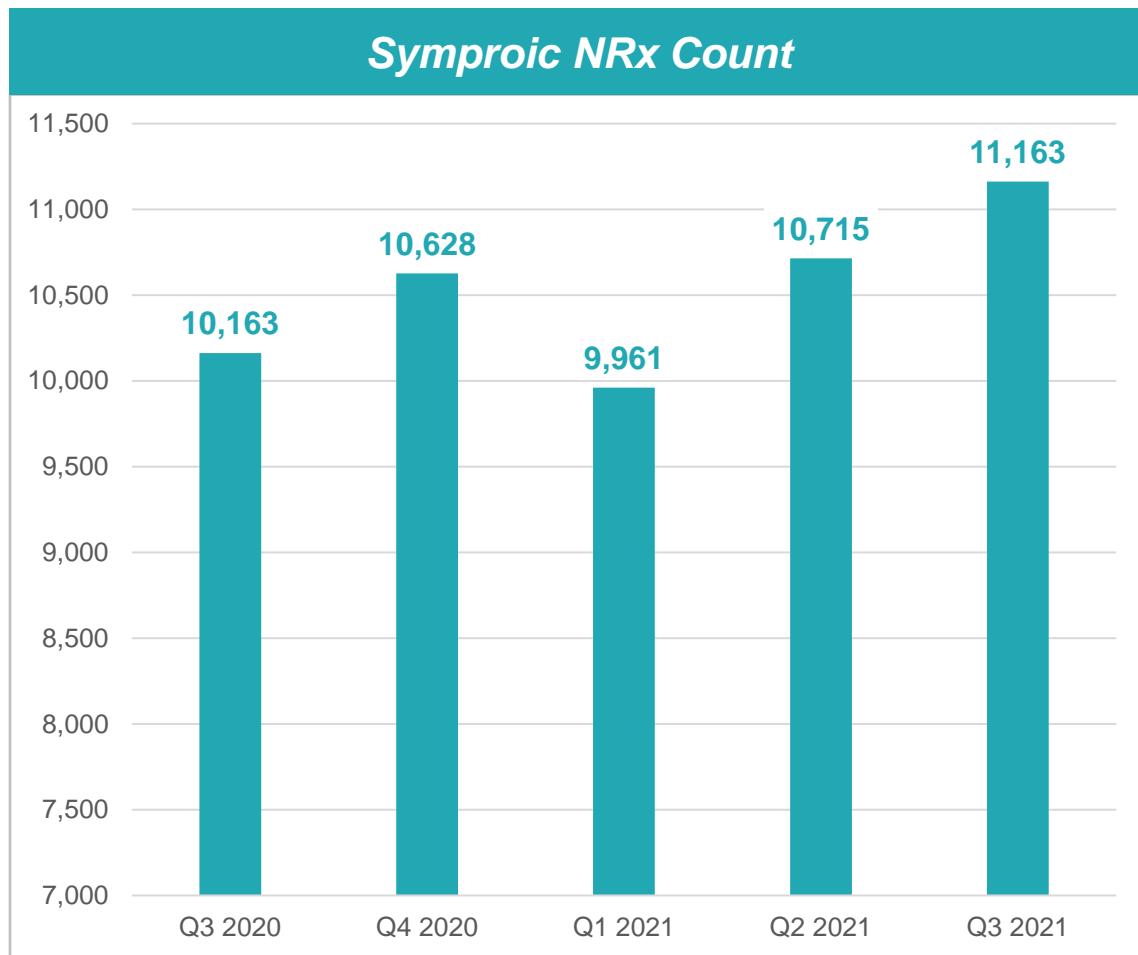
+1,000
New Prescribers in Q3 2021



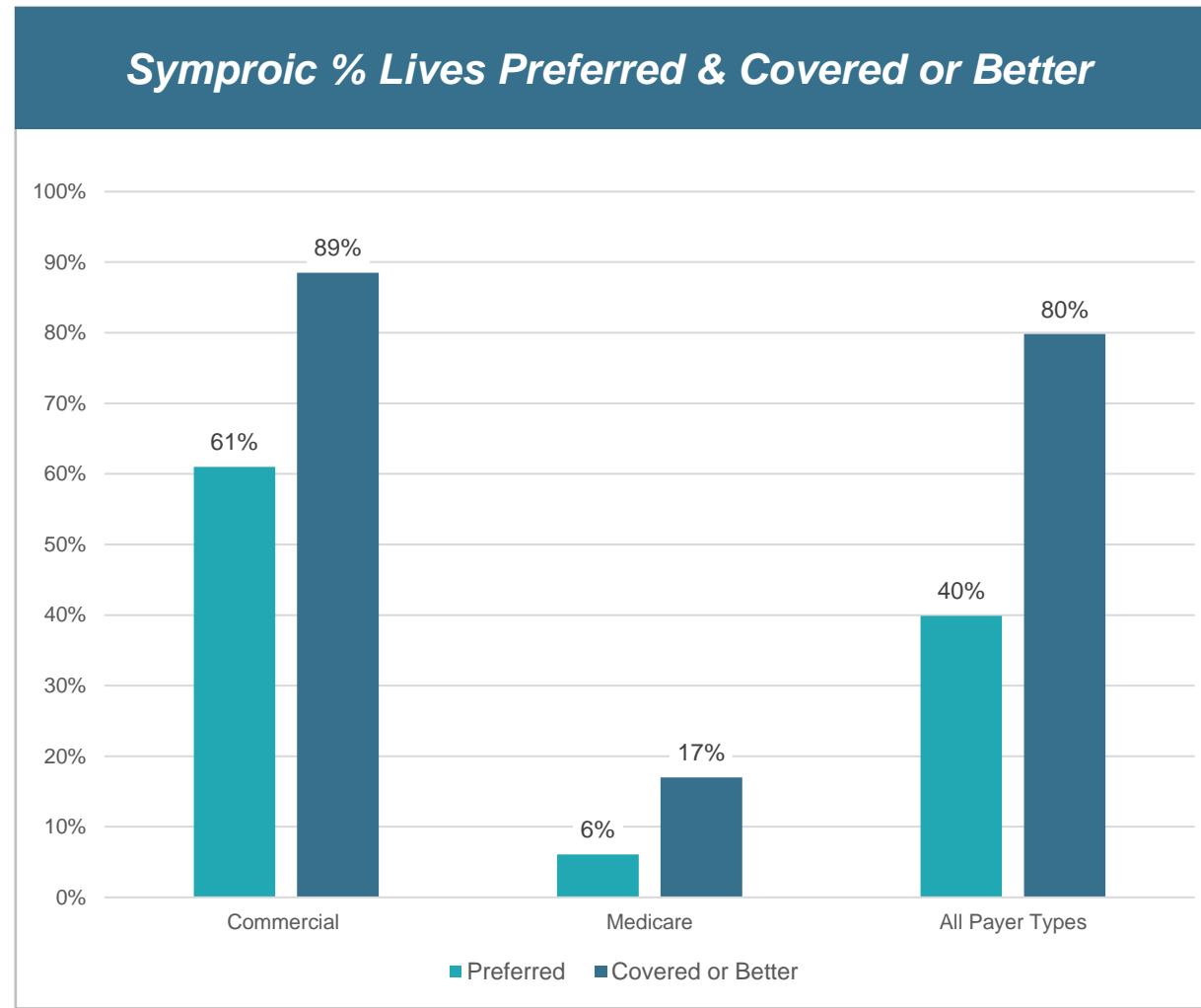
Source: Symphony Vantage Application

Symproic NRx Count Reached a New High in Q2

Symproic NRx Count Increased +9.8% YoY Leading to Record NRx Share of 14.3%



Symproic Favorable Formulary Coverage Continues



BELBUCA & Symproic TRx Growth Relative to Market (Retail TRx Data)

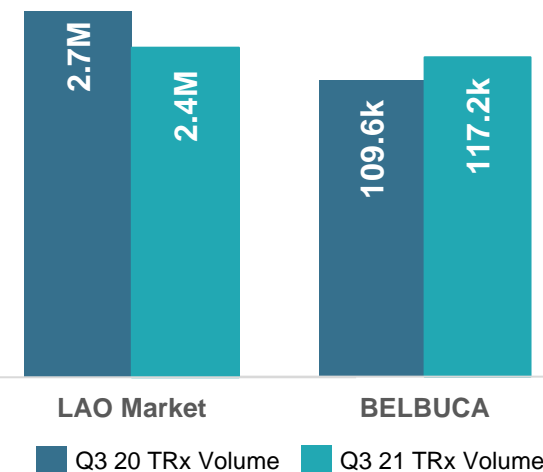
BELBUCA 2020 vs 2019

-10.0% LAO Market TRx Volume Decline
+29.8% BELBUCA TRx Volume Growth



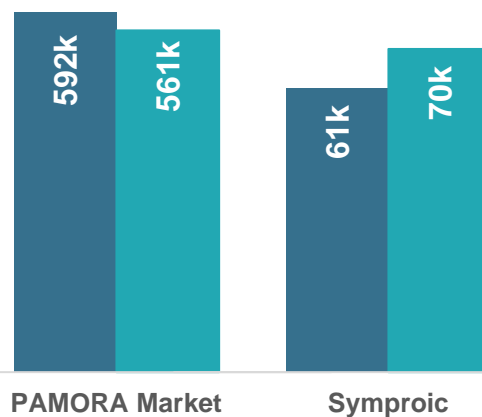
BELBUCA Q3 2021 vs Q3 2020

-10.0% LAO Market TRx Volume Decline
+6.9% BELBUCA TRx Volume Growth



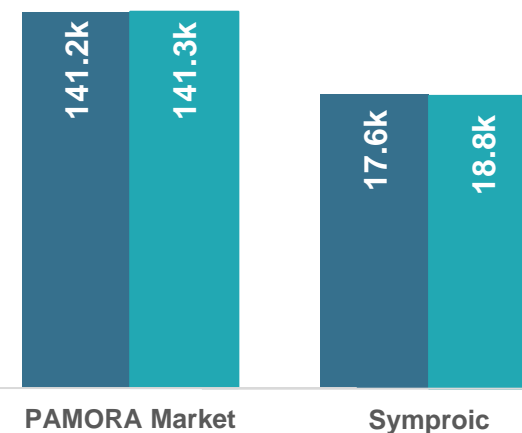
Symproic 2020 vs 2019

-5.1% PAMORA Market TRx Volume Decline
+13.9% Symproic TRx Volume Growth



Symproic Q3 2021 vs Q3 2020

+0.1% PAMORA Market TRx Volume Growth
+6.9% Symproic TRx Volume Growth



ELYXYB Expands BDSI's Presence in Neurology in Attractive Deal

Potential long-term peak sales opportunity of \$350 - \$400M

Differentiated Product in a Large & Growing Market

- The only FDA-approved, ready-to-use oral solution for the acute treatment of migraine with or without aura in adults
- Benefits from strong growth of the substantial and evolving migraine market
- Potential for pediatric label expansion, an additional indication for the treatment of acute pain, and includes the rights to commercialize in Canada.

Deal Rationale

- Highly attractive opportunity to diversify our product portfolio
- First in a series of steps to build a growth platform in Neurology
- Leverages BDSI team's commercial expertise and much of commercial and corporate infrastructure
- Patent protection until 2036
- Projected to be accretive approximately 24 months from commercial launch
- Q1 2022 Launch planned

Attractive Product Profile

- Headache pain freedom at 2 hours post-dose**
- Most Bothersome Symptom (MBS) freedom at 2 hours post-dose*
- Tmax of ~ 60 minutes
- Self-micro emulsifying drug delivery system that improves solubility and bioavailability of the drug leading to better absorption¹
- Extensive qualitative and quantitative market research indicated strong intent to prescribe by research participants

* Results of 2Pivotal studies comparing patients receiving ELYXYB to patients receiving placebo with the percentage of patients achieving MBS freedom at 2 hours post dose being significantly greater than patients receiving placebo
** Results of Pivotal study 2 comparing patients receiving ELYXYB to patients receiving placebo with the percentage of patients achieving headache pain freedom at 2 hours post dose being significantly greater than patients receiving placebo

1. Arindam Pal, Srinivas Shenoy, Anirudh Gautam, Sagar Munjal, Jing Niu, Mathangi Gopalakrishnan & Joga Gobburru, Clinical Drug Investigation volume 37, pages 937-946(2017)

ELYXYB: Attractive Growth Platform in Neurology

Pre-Launch Activities



 **Supply Chain Preparedness**

 **Sales Force Expansion**

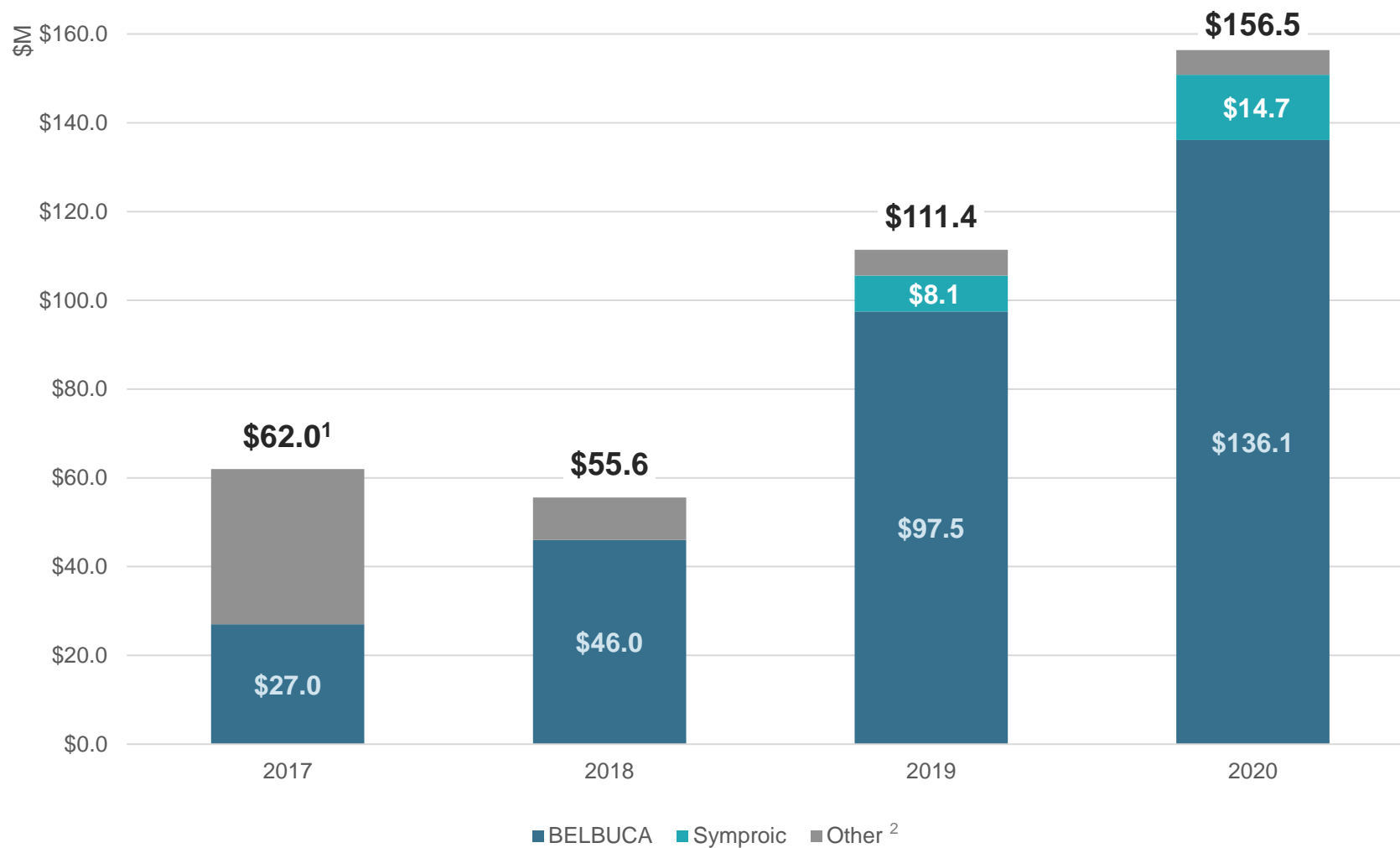
 **Training**

 **Development of Marketing Campaign for Launch**

 **KOL Engagement**

 **American Headache Society Conference**

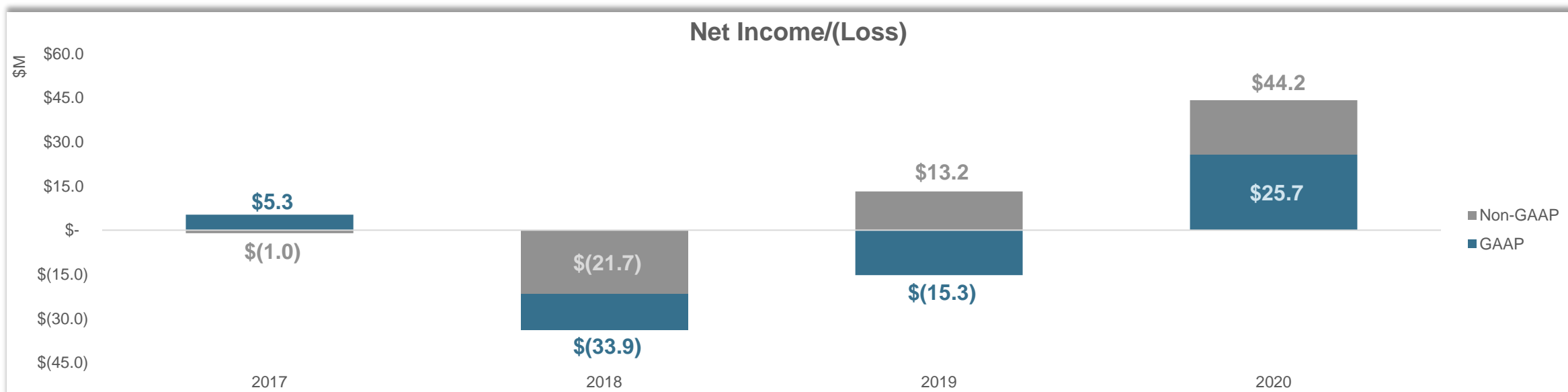
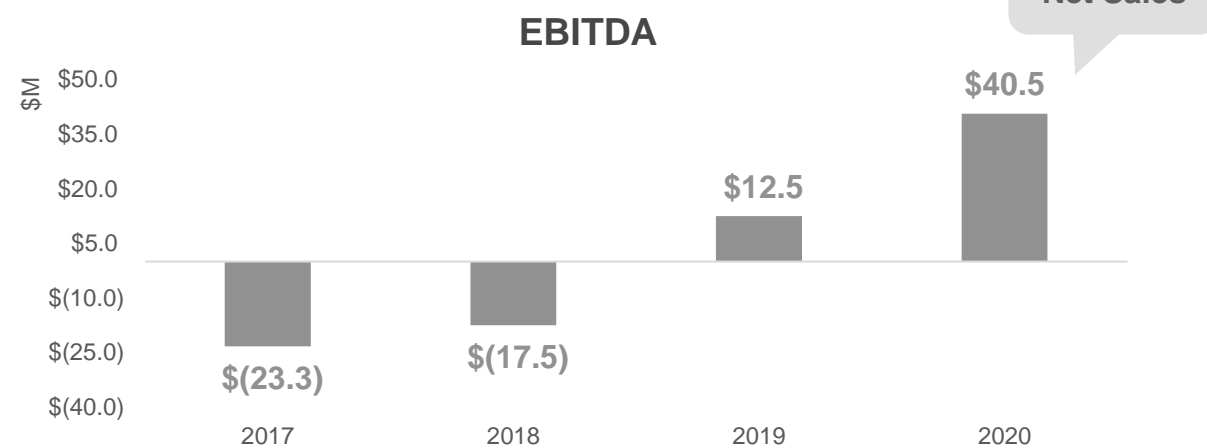
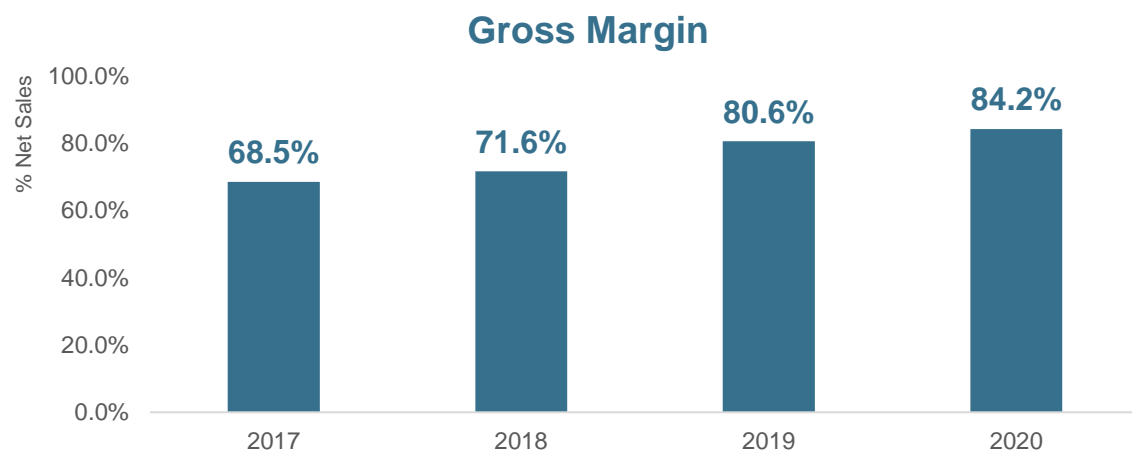
Robust Annual Net Revenue Growth Trends



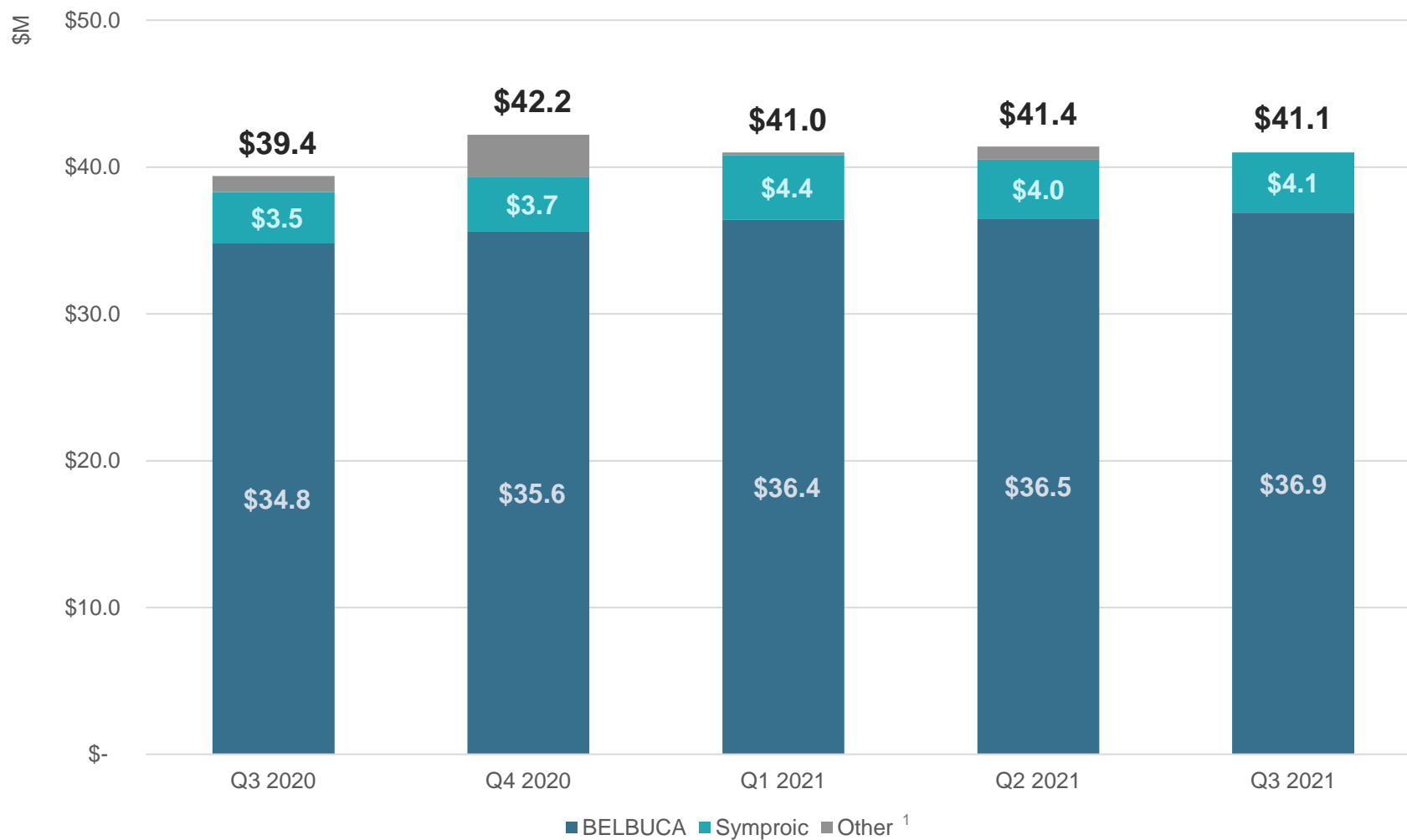
Total Net Revenue
+ 40%
 in 2020 vs. 2019

BELBUCA Revenue
+ 40%
 in 2020 vs. 2019

Sales Trajectory Driving Impressive Annual Gross Margin and Profitability



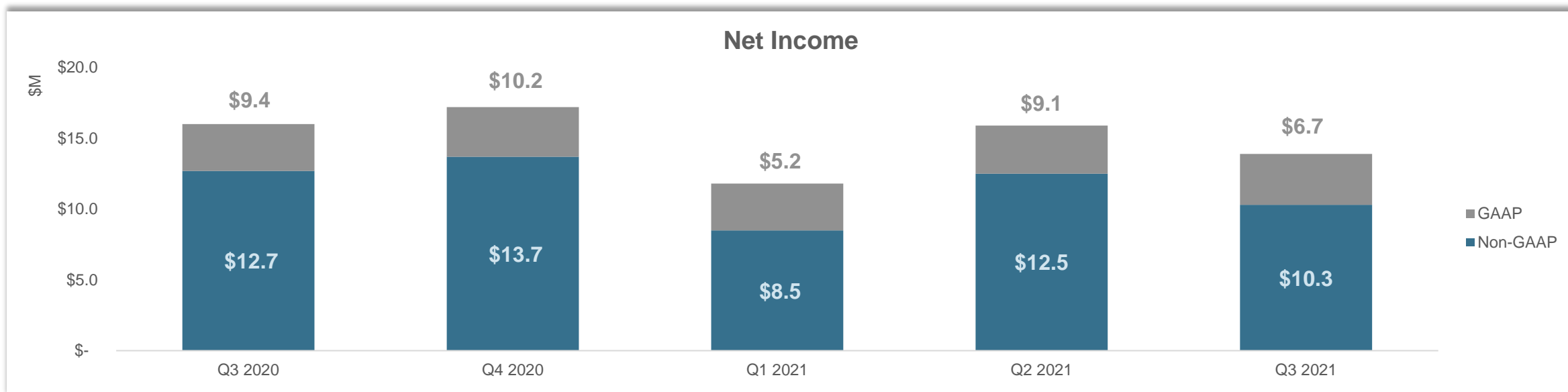
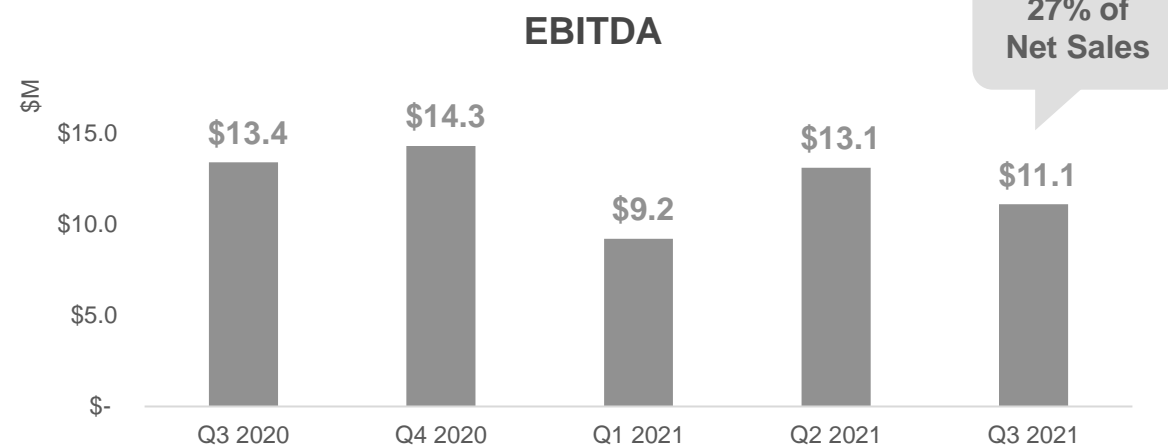
Q3 Total Year-over-Year Net Revenue Growth of 4%



**Q3 Record BELBUCA
Net Sales
\$36.9M**

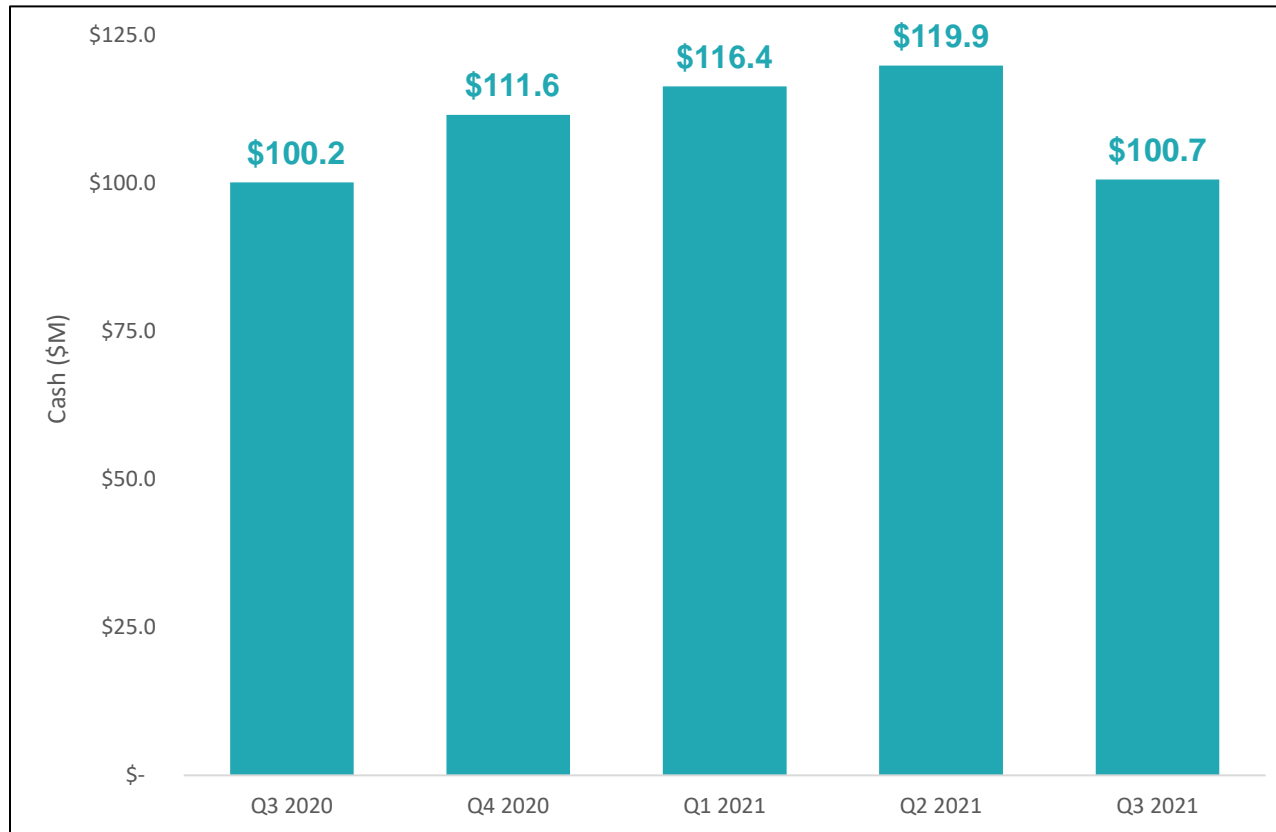
**Q3 YoY Symproic Net
Sales Growth
+20%**

Attractive EBITDA Margins Driven by Healthy Gross Margins While Continuing to Invest to Support Brand Growth



Continued Operating Cash Flow Generation in Q3 2021

Advantageously Positions BDSI to Support Continued Growth



As of September 30, 2021:

\$100.7M Cash and cash equivalents

\$ 60.0M Long Term Debt (reduced from \$80M)

Q3 2021 Total Cash Flow of (\$19M)

includes:

- Operating Cash flow generation of \$7M
- Debt pre-payment of \$20M
- \$6M upfront payment for ELYXYB

2021 Updated Expectations

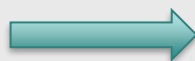
Total Company Net Sales



\$162 - \$167M

vs. \$170 - \$180M previously

BELBUCA Net Sales



\$144 - \$148M

vs. \$155 - \$165M previously

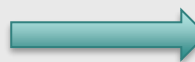
Total Operating Expenses



\$115 - \$120M

(Includes ELYXYB pre-launch spend)

EBITDA (Ongoing)



\$40 - \$50M

<\$40M including ELYXYB

Operating Cash Flow positive in 2021

Strong Performance in Q3 2021 and Positioned Well for Future Growth

Record Market Shares for BELBUCA & Symproic and Record BELBUCA Net Sales



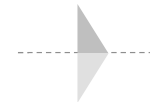
Record Product Market Share

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- Symproic **13.6%**

Record BELBUCA Net Sales in Q3



- Attractive 27% EBITDA Margin
- \$100.7M Cash Balance
- \$27.3M Operating Cash Flow Year to date 2021
- GAAP EPS \$0.07 vs \$0.05 consensus
- Strong balance sheet to support BDSI's growth



ELYXYB Acquisition Expands BDSI's Presence in Neurology

Product Launch On Track for Q1 2022

Reconciliation of GAAP to Non-GAAP Metrics

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
RECONCILIATION OF NON-GAAP METRICS
(U.S. DOLLARS, IN THOUSANDS)
(Unaudited)

	QTD- Q3 9/30/2020	QTD- Q4 12/31/2020	QTD- Q1 3/31/2021	QTD- Q2 6/30/2021	QTD- Q3 9/30/2021
	2020		2021		
Reconciliation of GAAP Net Income/(Loss) to EBITDA (non-GAAP)					
GAAP Net Income/(Loss)	\$ 9,383	\$ 10,197	\$ 5,237	\$ 9,064	\$ 6,669
Add back/(subtracts):					
Income tax recovery/(provision)	211	233	222	312	-
Net interest expense	2,012	2,022	1,979	1,999	1,984
Depreciation and amortization	1,754	1,806	1,753	1,769	1,837
EBITDA	\$ 13,360	\$ 14,259	\$ 9,191	\$ 13,144	\$ 10,490
Reconciliation of GAAP Net Income/(Loss) to Non-GAAP Net Income/(Loss)					
GAAP Net Income/(Loss)	\$ 9,383	\$ 10,197	\$ 5,237	\$ 9,064	\$ 6,669
Non-GAAP adjustments:					
Stock-based compensation expense	1,473	1,750	1,490	1,697	1,837
Amortization of intangible assets	1,734	1,733	1,735	1,735	1,795
Non-recurring financial impact- CEO transition	67	-	-	-	-
Non-GAAP Net Income/(Loss)	\$ 12,657	\$ 13,679	\$ 8,462	\$ 12,496	\$ 10,301